

16 December 2011

[25-11]

# **APPLICATION A1051 FOOD DERIVED FROM HERBICIDE-TOLERANT SOYBEAN LINE FG72 APPROVAL REPORT**

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## **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 approval 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 or New Zealand. Food derived from it would therefore enter the food supply 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 was assessed under the General Procedure.

### **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 had regard to the following matters as prescribed in s 29 of the FSANZ Act, in addition to considering the safety of food derived from soybean line FG72.

- 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 it contains novel DNA or novel protein.

#### **Decision**

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

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## Reasons for Decision

On the basis of the available evidence, the draft variation to the Code to allow the sale and use of food derived from herbicide-tolerant soybean line FG72 in Australia and New Zealand has been approved 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 from herbicide-tolerant soybean line FG72 is equivalent to that from other commercially available soybean cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of food derived from herbicide-tolerant 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

As this Application was assessed as a General Procedure, there was one round of public comment conducted over a period of six weeks; five submissions were received. A summary of these is provided in this Report at **Attachment 2**.

FSANZ has taken all submitters' comments into consideration in completing the assessment of this Application, and has addressed issues, particularly those relevant to the safety of food derived from soybean line FG72. Additional information was incorporated into the Safety Assessment where necessary.

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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/applicationa1051food4902.cfm>

SD1: Safety Assessment Report (Approval): 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.

FSANZ has completed a scientific evaluation of food derived from soybean line FG72 according to FSANZ guidelines (FSANZ 2007) to assess its safety for human consumption. The Assessment Report, including the proposed draft variation to the Code prepared in relation this Application, was released in August 2011 for a six week public consultation period. Comments received during this consultation period have been considered in completion of this Approval Report. All submissions relating to the Assessment Report have been summarised in **Attachment 2** to this Report.

### **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 COAG Legislative and Governance Forum on Food Regulation (FoFR)<sup>1</sup>. A variation to the Code may only be gazetted once the FoFR 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 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 Schedule to the Standard.

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<sup>1</sup> Previously known as the Australia and New Zealand Food Regulation Ministerial Council

## 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), Korea (Food and Drug Administration, Rural Development Administration) and the European Union (European Food Safety Authority - EFSA). These applications are still currently under consideration.

## 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.

## **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.

## 4. Risk Assessment Summary

### 4.1 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
- 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 have not been addressed in this assessment.

## 4.2 Outcomes of the Safety Assessment

The two novel gene cassettes were introduced into the parent line 'Jack' as a single linear DNA fragment. 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. The introduced DNA is stably inherited from one generation to the next. There are no antibiotic-resistance marker genes present in soybean line FG72.

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 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 to be as safe for human consumption as food derived from conventional soybean cultivars.

## **RISK MANAGEMENT**

### **5. Issues**

#### **5.1 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 (Liu et al. 1995). The main food product from field soybean is oil. Because the oil production process results in a highly refined product, both protein and DNA are unlikely to be present; the oil is therefore unlikely to require labelling. Other products such as protein concentrate, protein isolate and textured flour are likely to contain protein and DNA and, if so, would require labelling.

#### **5.2 Detection Methodology**

Recently, the Implementation Sub-Committee (ISC), a sub-committee of the 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. Since Bayer has also submitted an application to EFSA, there is a requirement, under Regulation (EC) No 1829/2003 of the European Parliament, for an event-specific detection methodology to be supplied for assessment and validation by the European Union Reference Laboratory for GMOs in Food and Feed. Once validated, this methodology is published by the European Commission Joint Research Centre on its GMO Detection Methods database (<http://gmo-crl.jrc.ec.europa.eu/gmomethods/>).

## **6. 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 provisions. 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, as follows, were available for consideration following the assessment:

### **Option 1 – Reject the draft variation**

Reject the draft variation, thus maintaining the *status quo*.

### **Option 2 – Approve the draft variation**

Approve the draft variation to permit the sale and use of food derived from soybean line FG72.

## **6.1 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 primarily in major soybean-growing countries. FSANZ understands there is currently no intention to apply for approval to cultivate this variety in either Australia or New Zealand. The cultivation of any GM crop 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 Protection Authority (EPA) in New Zealand, before commercial release in either country could be permitted.

## **6.2 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.

### *6.2.1 Option 1 – Reject the draft variation*

Consumers: Possible restriction in the availability of imported soybean 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 the food industry.

### *6.2.2 Option 2 – Approve the draft variation*

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.

### **6.3 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-derived foods.

Based on the conclusions of the safety assessments, the potential benefits of Option 2 outweigh the potential costs. Approval of a draft variation to Standard 1.5.2 to permit food derived from herbicide-tolerant soybean line FG72 was therefore the preferred option.

## **COMMUNICATION AND CONSULTATION STRATEGY**

### **7. Communication**

FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions are notified via media release and through FSANZ's social media tools and the publication *Food Standards News*. Subscribers and interested parties are also notified about the availability of Assessment Reports for public comment.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

Since 1 May 2011, FSANZ has been 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.

Application A1051 is already available on the website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1051food4902.cfm>. Submissions received on the Application are also available on the website.

The Applicant and individuals and organisations who made submissions on this Application were notified at each stage of the assessment. FSANZ Board decisions to approve

variations to the Code are notified to FoFR.

If the Board's decision to approve food derived from soybean line FG72 is not subject to a request for a review by FoFR, the Applicant and stakeholders, including the public, will be notified of the gazettal of the relevant changes to the Code in the national press and on the website.

## 8. Consultation

### 8.1 Public Consultation

As this Application was assessed under the General Procedure, there was one round of public consultation during which comments were specifically sought on the draft variation and scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from soybean line FG72.

Public submissions were invited on the Assessment Report between 19 August and 30 September 2011. Five submissions were received and comments relevant to food safety were considered in completing this Approval Report. All submissions have been summarised in **Attachment 2** to this Report.

#### 8.1.1 General issues

Responses to general issues raised, such as 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 *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
Data used to inform the Safety Assess.	Food Matters GM Foods <a href="http://www.foodstandards.gov.au/foodmatters/gmfoods/">http://www.foodstandards.gov.au/foodmatters/gmfoods/</a>

The main issues raised in submissions are discussed below.

#### 8.1.2 Specific issues

##### 8.1.2.1 Results from the safety assessment

The Food Technology Association of Australia was concerned that, of the 140 broilers used in the study, 77 showed clinical symptoms and 45 died yet the conclusion was that there was no treatment effect.

There were three treatment groups:

Group A – broilers fed seedmeal from the non-GM parental line

Group C – broilers fed seedmeal from GM soybean line FG72

Group D – broilers fed seedmeal from a non-GM commercial cultivar (Stine 3000-0)

There were 140 broilers in each group, making a total of 420 broilers used in the study.

The deaths and clinical symptoms were recorded for the three groups as follows

Group	Deaths	Clinical Symptoms
A	12	23
C	12	22
D	21	32
TOTAL	45	77

Of the 45 deaths, 23 were recorded from the 77 birds with clinical symptoms.

Statistical analyses of these results indicated no significant differences between groups.

#### 8.1.2.2 Analytical capability in Australia

Queensland Health was concerned that GM applications continue to be progressed when the Implementation Sub-Committee Expert Advisory Group (EAG), designed to consider detection methodology, has not yet been formed.

The information that would be required to be given to the EAG would be the full sequence data for the insert. Using this, any analytical laboratory would have the capability to develop a detection method. This sequence information has been supplied by the Applicant, although it is currently CCI and would therefore have restricted access. Since approval to commercially grow soybean FG72 has not yet been given in any country, food derived from this line would not yet be expected to enter the food supply.

#### 8.1.2.3 Labelling of bee pollen

Queensland Health requested information on how bee pollen derived from soybean FG72 would be labelled.

As with any GM food, this product as a discrete product sold as 'bee pollen', would require labelling if novel DNA or novel protein were present.

### **8.2 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.

Varying the Code to allow food derived from soybean line FG72 would have a trade enabling effect as it would permit the food to be imported into Australia and New Zealand and sold, where currently it is prohibited. Therefore, notification to the WTO under Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements was not considered necessary.

## **CONCLUSION**

### **9. Conclusion and Decision**

## **Decision**

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

### **9.1 Reasons for Decision**

On the basis of the available evidence, the draft variation to the Code to allow the sale and use of food derived from herbicide-tolerant soybean line FG72 in Australia and New Zealand has been approved 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 from herbicide-tolerant soybean line FG72 is equivalent to that from other commercially available soybean cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of food derived from herbicide-tolerant 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 the draft variation 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.

## **10. Implementation and Review**

The proposed variation to the Code will come into effect on Gazettal.

## **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%202 .pdf](http://www.foodstandards.gov.au/srcfiles/GM%20FINAL%20Sept%2007L%202.pdf)

Liu KS, Orthoefer F, Thompson K (1995) The case for food-grade soybean varieties. *INFORM* 6(5):593–599

## **ATTACHMENTS**

1. Variation to the *Australia New Zealand Food Standards Code*
2. Explanatory Statement
3. Summary of submissions

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



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

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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	
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### Explanatory Statement

#### 1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).<sup>2</sup>

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1051 which seeks permission for the sale and use of food derived from herbicide-tolerant soybean line FG72. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft Standard.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation<sup>2</sup>, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

#### 2. Purpose and operation

As it is not listed in the Schedule to Standard 1.5.2, food derived from soybean line FG72 is not currently permitted for sale or use in food. Therefore, FSANZ is proposing to vary Standard 1.5.2 by including food derived from soybean line FG72 in the Schedule.

#### 3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

#### 4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1051 included one round of public consultation following an assessment and the preparation of a draft variation. A Report (which included the draft Standard) was released for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the use of food derived from soybean line FG72, if approved, would be voluntary and would be likely to have a minor impact on business and individuals.

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<sup>2</sup> Previously known as the Australia and New Zealand Food Regulation Ministerial Council

## **5. Variation**

### **5.1 *Item [1]***

This item adds food derived from soybean line FG72 into the Schedule to Standard 1.5.2.

## Attachment 3

### Summary of issues raised in Assessment public submissions

Submitter	Comments
Paul Elwell-Sutton (Private)	<ul style="list-style-type: none"> <li>• Opposes approval for the following reasons               <ul style="list-style-type: none"> <li>- the toxicity studies are not independent and are therefore likely to be biased by the Applicant's interests.</li> <li>- FSANZ has not demonstrated that the decisions it makes are independent of an Applicant's interests</li> </ul> </li> </ul>
Hugh Halliday (Private)	<ul style="list-style-type: none"> <li>• This was a non-specific submission requesting support for a cause entitled 'Help Declare NZ GE/GM Free'</li> </ul>
Food Technology Association of Australia	<ul style="list-style-type: none"> <li>• Supports approval of the Application</li> <li>• Raises some concerns about the results of the animal feeding study and asks for an explanation.</li> </ul>
Ministry of Agriculture and Forestry (NZ)	<ul style="list-style-type: none"> <li>• Neither opposes nor supports approval of the Application.</li> <li>• Requests clarification of the results for Vitamin A in the compositional analysis.<sup>3</sup></li> <li>• Points out some typographical errors<sup>4</sup>.</li> </ul>
Queensland Health (whole of Government response)	<ul style="list-style-type: none"> <li>• Neither opposes nor supports approval of the Application.</li> <li>• Requests advice on progress of FG72 applications made to other regulatory agencies<sup>5</sup>.</li> <li>• Expresses concern about the availability of analytical capability in Australia.</li> <li>• Requests information on the labelling of bee pollen.</li> <li>• Requests a copy of the letter sent to FSANZ from the OBPR re GM food applications<sup>6</sup>.</li> <li>• Points out some typographical errors<sup>2</sup>.</li> </ul>

<sup>3</sup> Now included in the Safety Assessment (SD1)

<sup>4</sup> Typographical errors corrected

<sup>5</sup> Status as at 27 October 2011 is included in this Approval Report

<sup>6</sup> Email containing the letter was sent on 5 October 2011