

**9 November 2017**

**[32–17]**

## **Call for submissions – Application A1147**

### **Food derived from Herbicide-tolerant Cotton Line GHB811**

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FSANZ has assessed an Application made by Bayer CropScience Pty Ltd to seek approval for food derived from dual-herbicide tolerant cotton line GHB811 and has prepared a draft variation of a food regulatory measure. Cotton line GHB811 has been genetically modified to provide tolerance to the herbicides glyphosate and isoxaflutole. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft variation.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly 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 via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 21 December 2017**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Hard copy submissions may be sent to one of the following addresses:

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KINGSTON ACT 2604  
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Tel +61 2 6271 2222

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### Supporting document

The [following documents](#)<sup>1</sup> which informed the assessment of this Application are available on the FSANZ website:

SD1        Safety Assessment Report

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<sup>1</sup> <http://www.foodstandards.gov.au/code/applications/Pages/A1147.aspx>

## Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Bayer CropScience Pty Ltd requesting a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to include food derived from a new genetically modified (GM) cotton (*Gossypium hirsutum*) line, GHB811. This cotton line has been genetically modified for dual-herbicide tolerance to glyphosate and isoxaflutole.

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

The safety assessment of GHB811 is provided in Supporting Document 1. No potential public health and safety concerns have been identified. Based on the data provided and other available information, food derived from cotton line GHB811 is considered to be as safe for human consumption as food derived from conventional cotton cultivars.

FSANZ has prepared a draft variation to Schedule 26 that includes a reference to food derived from cotton line GHB811.

# 1 Introduction

## 1.1 The Applicant

Bayer CropScience Pty Ltd (Bayer) is a technology provider to sectors including agriculture.

## 1.2 The Application

Application A1147 was submitted on 1 May 2017. It seeks a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to include food from a new genetically modified (GM) cotton (*Gossypium hirsutum*) line, GHB811. This cotton line has been genetically modified for dual-herbicide tolerance to glyphosate and isoxaflutole.

Tolerance to herbicides containing glyphosate is achieved with the expression of a modified corn-derived gene *2mepsps*, which encodes a modified 5-enolpyruvylshikimate-3-phosphate synthase (2mEPSPS) enzyme. The 2mEPSPS differs from the original corn protein by two amino acids. Tolerance to isoxaflutole is achieved by the expression of a modified p-hydroxyphenyl pyruvate dioxygenase (HPPD) enzyme, encoded by the *hppdPf W336* gene derived from the soil bacterium *Pseudomonas fluorescens*. The modified HPPDPf W336 enzyme contains a single amino acid change.

The safety of both proteins has previously been assessed by FSANZ.

The Applicant has indicated that food derived from GHB811 may be used in food as cottonseed oil and linters. Cottonseed oil may be used in foods such as frying oil, salad and cooking oil, and as an ingredient in mayonnaise, salad dressing, shortening, and margarine.

Linters are the short fibres that coat the seeds and are a by-product of oil extraction from cotton seeds. Linters can be processed into forms of cellulose that may be used in certain food additives, for example anticaking agents and thickeners. Other food uses include casings for processed meats.

## 1.3 The current standard

Pre-market approval is necessary before a genetically modified (GM) food may enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment. Standard 1.5.2 – Food produced using gene technology, sets out the permission and conditions for the sale of food that consists of, or has as an ingredient, a food produced using gene technology (a GM food). Foods that have been assessed and approved are listed in Schedule 26.

Section 1.5.2—4 of Standard 1.5.2 also contains specific labelling provisions for approved GM foods. Subject to certain exceptions listed below, GM foods and ingredients (including food additives and processing aids from GM sources) must be identified on labels with the words ‘genetically modified’, if novel DNA or novel protein (as defined in Standard 1.5.2) is present in the food.

Foods listed in subsections S26—3(2) and (3) of Schedule 26 are considered to have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not produced using gene technology. Foods listed in subsections S26—3(2) and (3) must also be labelled with the words ‘genetically modified’, as well as any other additional labelling required by the Schedule, regardless of the presence of novel DNA or novel protein in the foods.

The requirement to label food as 'genetically modified' does not apply to GM food that:

- has been highly refined (other than food that has been altered), where the effect of the refining process is to remove novel DNA or novel protein
- is a substance used as a processing aid or a food additive, where novel DNA or novel protein from the substance does not remain present in the final food
- is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%)
- is intended for immediate consumption and which is prepared and sold from food premises and vending machines, including restaurants, take away outlets, caterers, or self-catering institutions
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient.

If the GM food for sale is not required to bear a label, the labelling information in section 1.5.2—4 must accompany the food or be displayed in connection with the display of the food (in accordance with subsections 1.2.1—9(2) and (3) of Standard 1.2.1 (Requirements to have labels or otherwise provide information)).

## **1.4 Reasons for accepting Application**

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

## **1.5 Procedure for assessment**

The Application is being assessed under the General Procedure.

# **2 Summary of the assessment**

## **2.1 Safety assessment**

In conducting a safety assessment of food derived from GHB811, a number of criteria have been addressed including: a characterisation of the transferred gene sequences, their origin, function and stability in the cotton genome; the changes at the level of DNA and protein in the whole food; compositional analyses and evaluation of intended and unintended changes.

The assessment of GHB811 was restricted to human food safety and nutritional issues. This assessment therefore does not address any risks to the environment that may occur as the result of growing GM plants used in food production, or any risks to animals that may consume feed derived from GM plants. The Applicant has no intention at this stage to apply for commercial cultivation of GHB811 in Australia or New Zealand. This would require independent assessment and approval by the Office of the Gene Technology Regulator in Australia. Should cultivation in New Zealand be sought, this would require assessment by the Environmental Protection Authority in New Zealand.

No potential public health and safety concerns have been identified.

Based on the data provided in the Application, and other available information, food derived from GHB811 is considered to be as safe for human consumption as food derived from conventional cotton cultivars.

## **2.2 Risk management**

### **2.2.1 Labelling**

#### ***2.2.1.1 Requirement to be labelled as ‘genetically modified’***

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food derived from GHB811 would be required to be labelled as ‘genetically modified’ if it contains novel DNA or novel protein or is listed in subsections S26—3(2) and (3) of Schedule 26 as being subject to the condition that the labelling must comply with section 1.5.2—4 of Standard 1.5.2 (such food has altered characteristics). FSANZ has determined that food derived from GBH811 does not have altered characteristics.

Cottonseed oil and linters are the major products of GHB811 intended for human consumption. Cottonseed oil is unlikely to contain novel DNA or novel protein due to the extensive refining process used to extract the oil from the seed. However, if novel DNA or novel protein was present, the labelling statement would be required.

Cottonseed linters are also highly purified and unlikely to contain novel DNA or novel protein (linters are essentially pure cellulose), therefore products containing linters from GHB811 would be unlikely to require labelling. Similarly, the presence of novel DNA or novel protein would trigger the labelling requirement.

### **2.2.2 Detection methodology**

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions, was formed by the Food Regulation Standing Committee’s Implementation Sub-Committee<sup>2</sup> to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food produced using gene technology (GM applications).

The EAG indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the Applicant for A1147.

## **2.3 Risk communication**

### **2.3.1 Consultation**

Consultation is a key part of the FSANZ standards development process.

FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release, through FSANZ’s social media tools and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

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<sup>2</sup> Now known as the Implementation Subcommittee for Food Regulation

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received on this call for submissions.

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 Forum on Food Regulation. If the Board's decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code.

### **2.3.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members 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.

There are no relevant international standards and amending the Code to permit food derived from GHB811 is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## **2.4 FSANZ Act assessment requirements**

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

### **2.4.1 Section 29**

#### **2.4.1.1 Consideration of costs and benefits**

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010, granted a standing exemption from the need for the OBPR to assess if a Regulatory Impact Statement is required for the approval of genetically modified foods (OBPR ref 12065).

This standing exemption was provided because these changes are considered as minor, machinery and deregulatory in nature. The exemption relates to the introduction of a food to the food supply that has been determined to be safe.

Notwithstanding the above exemption, FSANZ conducted a cost benefit analysis. That analysis found the direct and indirect benefits that would arise from varying a food regulatory measure, as a result of the Application, outweigh the costs to the community, government or industry that would arise from the variation of that measure.

A consideration of the cost/benefit of the regulatory options is not intended to be an exhaustive, quantitative financial analysis of the options as 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.

The options below are based on cotton containing event GHB811 being approved for growing in other countries since the Applicant has stated that approval for cultivation in Australia or New Zealand is not currently being sought. Cultivation in Australia or New Zealand would require separate regulatory approval (see section 2.4.1.4).

*Option 1 – Prepare a draft variation of Schedule 26*

**Consumers:** Food containing event GHB811 has been assessed as being as safe as food from conventional lines of cotton.

There would be broader availability of imported cotton products since, if GHB811 is approved for commercial growing in other countries, there would be no restriction on imported foods containing this line.

For those GHB811 food products containing novel DNA or novel protein, required labelling would allow consumers wishing to avoid these products to do so.

If GHB811 is approved for commercial growing in either overseas countries or Australia it could be used in the manufacture of products using co-mingled cotton seed. This means that there would be no cost involved in having to exclude GHB811 seed from co-mingling and hence that there would be no consequential need to increase the prices of foods that are manufactured using co-mingled cotton seed.

**Government:** Approval would avoid any conflict with WTO obligations. As mentioned above, food from GHB811 has been assessed as being as safe as food from conventional lines of cotton.

This option would be cost neutral in terms of compliance costs, as monitoring is required irrespective of whether or not a GM food is approved.

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.

**Industry:** Foods derived from GHB811 would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of seed of GHB811 from conventional cotton seed, as for any GM crop, will be driven by industry, based on market preferences. Implicit in this will be a due regard to the cost of segregation.

Retailers may be able to offer a broader range of cotton products or imported foods manufactured using cotton derivatives.

There may be additional costs to the food industry as food ingredients derived from GHB811 would require the 'genetically modified' labelling statement if they contain novel DNA or novel protein.

### *Option 2 – Reject application*

**Consumers:** Possible restriction in the availability of imported cotton products which may be produced after co-mingling of seed from GHB811.

No effect on consumers wishing to avoid GM foods, as food from GHB811 is not currently permitted in the food supply.

Potential increase in price of imported cotton food products due to requirement for segregation of GHB811 seed.

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

**Industry:** Possible restriction on imports of cotton food products, if GHB811 is commercialised overseas.

As food from GHB811 has been found to be as safe as food from conventional lines of cotton, not preparing a draft variation offers little benefit to consumers, as approval of GHB811 by other countries could limit the availability of imported cotton products in the Australian and New Zealand markets.

#### **2.4.1.2 Other measures**

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than varying Schedule 26 as a result of Application A1147.

#### **2.4.1.3 Any relevant New Zealand standards**

Standard 1.5.2 and Schedule 26 apply in both Australia and New Zealand. There is no relevant New Zealand only standard.

#### **2.4.1.4 Any other relevant matters**

The Applicant has submitted applications for regulatory approval of GHB811 to a number of other countries, as listed in Table 1.

The Applicant has stated they currently have no intention to apply for approval to cultivate GHB811 in Australia and New Zealand. Cultivation in Australia or New Zealand would require independent assessment and approval by the OGTR and NZ EPA respectively.

**Table 1: List of countries to whom applications for regulatory approval of GHB811 have been submitted**

Country	Agency	Type of approval sought	Status
United States of America	United States Department of Agriculture	Environmental release and cultivation	Under review
	Food and Drug Administration	Food and feed	Under review
Canada	Health Canada	Food	Under review
Korea	Rural Development Administration	Food and feed	Under review
	Ministry of Food and Drug Safety	Food	Under review

Further other relevant matters are considered below.

#### **2.4.2. Subsection 18(1)**

FSANZ has also had regard to the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

##### **2.4.2.1 Protection of public health and safety**

Food derived from GHB811 has been assessed based on the data requirements provided in the FSANZ [Application Handbook](#)<sup>3</sup> which, in turn reflect internationally-accepted GM food safety assessment guidelines. No public health and safety concerns were identified in this assessment. Based on the available evidence, including detailed studies provided by the Applicant, food derived from GHB811 is considered as safe and wholesome as food derived from other commercial cotton lines.

##### **2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

In accordance with existing labelling provisions in the Code, food derived from GHB811 would be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see Section 2.2.1).

##### **2.4.2.3 The prevention of misleading or deceptive conduct**

The provision of detection methodology by the Applicant (as described in Section 2.2.2) addresses this objective.

#### **2.4.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2004). Based on these principles, the risk analysis undertaken for GHB811 used the best scientific evidence available. The Applicant submitted to FSANZ a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the Applicant, other available resource material including published scientific literature and general technical information was used in the safety assessment.

- **the promotion of consistency between domestic and international food standards**

This is not a consideration as there are no relevant international standards.

- **the desirability of an efficient and internationally competitive food industry**

The inclusion of GM foods in the food supply, providing there are no safety concerns, allows for innovation by developers and a widening of the technological base for the production of

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<sup>3</sup> <http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

foods. Cotton line GHB811 is a new food crop designed to provide growers with an alternative broad spectrum herbicidal mode of action for cotton farming systems.

- **the promotion of fair trading in food**

Issues, related to consumer information and safety, are considered in Section 2.2 and 2.3 above.

- **any written policy guidelines formulated by the Forum on Food Regulation**

No specific policy guidelines have been developed.

### **3 Draft variation**

The draft variation to the Code is at Attachment A and is intended to take effect on the date of gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

### **4 References**

Codex (2004) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome. <http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/>

### **Attachments**

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

## Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



### Food Standards (Application A1147 – Food derived from Herbicide-tolerant Cotton Line GHB811) 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 variation commences on the date specified in clause 3 of the variation.

Dated [To be completed by Standards Management Officer]

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

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

**1 Name**

This instrument is the *Food Standards (Application A1147 – Food derived from Herbicide-tolerant Cotton line GHB811) Variation*.

**2 Variation to a Standard in the *Australia New Zealand Food Standards Code***

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

**3 Commencement**

The variation commences on the date of gazettal.

**Schedule**

**[1] Schedule 26** is varied by inserting in the table to subsection S26—3(4) in alphabetical order under item 3

- (o) herbicide-tolerant cotton line GHB811

## **Attachment B – Draft 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).

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 A1147 which seeks approval for food derived from cotton line GHB811, genetically modified to provide tolerance to isoxaflutole and glyphosate. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

### **2. Purpose**

The purpose of the draft variation is to permit the sale of food derived from genetically modified cotton line GHB811.

### **3. Documents incorporated by reference**

The variations to food regulatory measures do 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 A1147 will include one round of public consultation following an assessment and the preparation of a draft variation.

A Regulation Impact Statement was not required because the sale of food derived from cotton line GHB811, if approved, would be voluntary and would be likely to have a minor impact on business and individuals (see OBPR ref 12065).

### **5. Statement of compatibility with human rights**

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

### **6. Variation**

Item [1] inserts new paragraph (o) into item 3 in the table to subsection S26—3(4) in Schedule 26. The new paragraph refers to 'herbicide-tolerant cotton line GHB811'. The effect of the variation is to permit the sale of food derived from that cotton line in accordance with Standard 1.5.2.