

20 March 2018
[41-18]

Approval report – Application A1147

Food derived from Herbicide-tolerant Cotton Line GHB811

Food Standards Australia New Zealand (FSANZ) has assessed an Application made by Bayer CropScience Pty Ltd to seek approval for food derived from cotton line GHB811, genetically modified to provide resistance to isoxaflutole and glyphosate.

On 9 November 2017, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received 4 submissions.

FSANZ approved the draft variation on 8 March 2018. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 14 March 2018.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD	3
1.4 REASONS FOR ACCEPTING APPLICATION	4
1.5 PROCEDURE FOR ASSESSMENT	4
1.6 DECISION	4
2 SUMMARY OF THE FINDINGS	4
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	4
2.2 SAFETY ASSESSMENT	6
2.3 RISK MANAGEMENT	6
2.4 RISK COMMUNICATION.....	7
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS	7
3 REFERENCES	ERROR! BOOKMARK NOT DEFINED.
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	12
ATTACHMENT B – EXPLANATORY STATEMENT	14

Supporting document

The [following document](#)¹ which informed the assessment of this Application is available on the FSANZ website:

SD1 Safety Assessment Report (at Approval)

¹ <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 on 1 May 2017 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.

The FSANZ Board has approved the 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 enzyme 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 HPPDPfW336 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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

The related 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.

2 Summary of the findings

2.1 Summary of issues raised in submissions

A total of four submissions were received of which one was opposed to the proposed draft variation to Schedule 26 and another requested further information, which is addressed in Table 1.

The single submission that opposed the proposal, raised several concerns that are outside the scope of FSANZ's regulatory framework. For example, issues were raised about the social impact, environmental issues, farming practices, and more generalised GM issues not related to the cotton line assessed in this application. A concern that was raised about labelling has been addressed in Table 1.

Table 1: Responses to issues raised

Issue	Raised by	FSANZ response
Sought full labelling of all GM food due to safety concerns	Yosephine Deans	<p>Only those GM foods assessed by FSANZ as safe are approved for sale. The labelling of approved GM foods is therefore not for safety reasons; labelling is to assist consumers to make an informed choice about the food they buy. Australia's and New Zealand's GM food labelling laws are based on the presence of GM material or altered characteristics in the final food ('product-based' labelling) rather than 'process-based' labelling which is based solely on the production method, irrespective of the presence of GM material or altered characteristics in the final food.</p> <p>The current labelling laws for GM foods in Australia and New Zealand were decided by the Australia and New Zealand Food Regulation Ministerial Council (now known as The Australia and New Zealand Ministerial Forum on Food Regulation – the Forum). The Forum's decision to base GM labelling on the final food product sought to balance the need for consumers to be provided with meaningful information, against the need for such requirements to be practical and enforceable.</p> <p>In December 2011, the Forum responded to recommendations contained in Labelling Logic: Review of Food Labelling Law and Policy (2011). In its response, the Forum supported the continuation of the current GM labelling provisions in the Food Standards Code and agreed not to pursue any additional regulatory requirements. Further information on Labelling Logic and the government response is available from the Food Regulation website².</p>
Requested further information about the absence of a maximum residue limit (MRL) for cotton seed treated with isoxaflutole in Schedule 20 – Maximum residue limits	Department of Health QLD	<p>The Submitter has noted correctly that currently there is no MRL for isoxaflutole on cotton seed listed in Schedule 20 of the Code. For GM foods derived from crops that are herbicide tolerant, there are two issues that require consideration. The first is dealt with in the safety assessment and involves consideration of any novel metabolites that are produced after the herbicide is applied, to determine whether these are present in the final food and whether their presence raises any toxicological concerns. This was addressed in Section 4.4 of SD1.</p> <p>The second consideration, which is separate from the GM food approval process and therefore not included as part of the safety assessment, relates to the presence of herbicide residues on the food. Any food products (whether derived from GM or non-GM sources) sold in both Australia and New Zealand must not have residue levels greater than the relevant MRL. Where necessary, an MRL may have to be set and in the case of GHB811, the Applicant is currently going through this process. The first step is to have an MRL for isoxaflutole in cotton set by authorities in the country where GHB811 will be grown – in this case the USA. Once this is obtained and in order for the food to be imported and sold in Australia, the Applicant can make a request to FSANZ to harmonise the MRLs and amend Schedule 20 of the Code as outlined on the FSANZ website (see Chemicals in food - maximum residue limits³). For importation and sale in New Zealand, a request can be made with the NZ Ministry for Primary Industries (MPI) to establish an MRL for an agricultural compound and amend the MRL Notice, as outlined on the MPI website (see Maximum residue levels for agricultural compounds⁴).</p>

² <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/Review-of-food-labelling>

³ <http://www.foodstandards.gov.au/consumer/chemicals/maxresidue/Pages/default.aspx>

⁴ <https://www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/maximum-residue-levels-for-agricultural-compounds/>

2.2 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 (OGTR) in Australia. Should cultivation in New Zealand be sought, this would require assessment by the Environmental Protection Authority in New Zealand (NZ EPA).

Some minor changes in the SD1 released with the call for submissions have been made to correct some minor typographical errors.

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.

2.3 Risk management

2.3.1 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.

2.3.2 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-Committee⁵ to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food

⁵ Now known as the Implementation Subcommittee for Food Regulation

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.

2.3.3 Maximum residue limit for isoxaflutole in cotton seed

In accordance with the requirements set out in Australian Food Standard 1.4.2 – Agvet chemicals and the Maximum Residue Limits Standard in the New Zealand *Food Act 2014*, GHB811 could not be imported or sold in Australia or New Zealand without an MRL for isoxaflutole in cotton. Currently, there is no MRL in Australia or New Zealand for isoxaflutole in cotton, however the Applicant has informed FSANZ that they are currently in the process of establishing an MRL in the USA. Once the MRL value has been determined, a further request can be made to FSANZ to amend Schedule 20 of the Code and to the NZ Ministry of Primary Industries to amend the Maximum Residue Levels for Agricultural Compounds Food Notice (MRL Notice) to harmonise the MRL with international limits. Once this harmonisation process has been completed then the importation and sale of GHB811 into Australia and New Zealand can be permitted.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions are requested to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

Public submissions were invited on a draft variation which was released for public comment between 9 November and 21 December 2017. The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media tools and the publication, Food Standards News. Subscribers and interested parties were also notified.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application.

Every submission on this Application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of the safety assessment.

Documents relating to Application A1147, including submissions received, are available on the FSANZ website.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 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 GM foods (ref 12065).

This standing exemption was provided as such 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 a food regulatory measure developed or varied as a result of the Application outweigh the costs to the community, government or industry that would arise from the development or 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 cost benefit analysis is based on 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 2.5.1.4).

Option 1 was selected.

Option 1 – Approve the draft variation to 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 the draft variation to Schedule 26

As food derived from cotton line GHB811 has been found to be as safe as food from conventional counterparts, not preparing a draft variation would offer little relative benefit to consumers, government and industry.

2.5.1.2 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.

2.5.1.3 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.

2.5.1.4 Any other relevant matters

The Applicant has submitted applications for regulatory approval of GHB811 to a number of other countries, as listed in Table 2.

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 2: 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

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

Food derived from GHB811 has been assessed based on the data requirements provided in the FSANZ [Application Handbook](#)⁶ 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.

2.5.2.2 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 2.3.1). This will enable consumers to make informed choices in relation to such food.

2.5.2.3 The prevention of misleading or deceptive conduct

The provision of detection methodology by the Applicant (as described in Section 2.3.2) addresses this objective.

2.5.3 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 foods. Cotton line GHB811 is a new food crop designed to provide growers with an

⁶ <http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

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 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. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*



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

Dated [to be completed by the Delegate]

[Name and position of General Manager responsible for A1147]
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 – 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.

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

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the 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 *Legislation Act 2003*.

2. Purpose

The purpose of this instrument is to amend the table to subsection S26—3(4) of Schedule 26 of the Code (permitted food produced using gene technology and conditions) to permit the use or sale of food derived from herbicide tolerant 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 9 November 2017 for a six-week consultation period.

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 (ref 12065). Therefore, a Regulation Impact Statement was not required in this case because the proposed variation to Schedule 26 is likely to have a minor impact on business and individuals.

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 use or sale of food derived from that cotton line in accordance with Standard 1.5.2.