

14 April 2020
[120–20]

Call for submissions – Application A1196

Food derived from nematode-protected and herbicide-tolerant soybean line GMB151

FSANZ has assessed an application made by BASF Agricultural Solutions Seed US LLC to seek approval for food derived from nematode-protected and herbicide-tolerant soybean line GMB151 and has prepared a draft food regulatory measure. 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 food regulatory measure.

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 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.

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) 9 June 2020

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.

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

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Supporting document

The following document which informed the assessment of this application are available on the [FSANZ website](#):

Supporting document 1 – Safety Assessment report

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from BASF Agricultural Solutions Seed US LLC 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) soybean (GMB151). This soybean line has been genetically modified to be protected from parasitic nematodes and tolerant to HPPD-inhibitor herbicides such as 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 GMB151 is in Supporting Document 1. No potential public health and safety concerns have been identified. Based on the data provided and other information, food derived from soybean line GMB151 is considered to be as safe for human consumption as food derived from conventional soybean cultivars.

FSANZ has prepared a draft variation to Schedule 26 that includes a reference to food derived from soybean line GMB151. The effect of the draft variation will be to permit the use or sale of food derived from that soybean line in accordance with the Code.

1 Introduction

1.1 The Applicant

BASF Agricultural Solutions Seed US LLC Australia Limited is a technology provider to a number of sectors including the agriculture sector.

1.2 The Application

Application A1196 was submitted on 29 November 2019. 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) soybean (*Glycine max*) line, GMB151. This soybean line has been genetically modified for nematode-protection and herbicide-tolerance.

Protection from parasitic nematodes is achieved through expression of the *Bacillus thuringiensis* (Bt) gene *cry14Ab-1.b*, which encodes a novel Bt crystal (Cry) protein Cry14Ab1. Tolerance to the herbicide isoxaflutole is achieved by the expression of a modified p-hydroxyphenyl pyruvate dioxygenase (HPPD) enzyme, encoded by the *hppdPf-4Pa* gene derived from the soil bacterium *Pseudomonas fluorescens*. The modified HPPD-4 enzyme contains four amino acid changes. Neither Cry14Ab1 nor HPPD-4 have previously been assessed by FSANZ.

The applicant has indicated the type of food derived from GMB151 will be soybean oil and soybean meal products. Refined soybean oil in both liquid or partially hydrogenated forms can be used in products like vegetable oils, margarine, shortening, salad dressings and imitation dairy and meat products. Soybean meal is the basis for soy milk and can be used as a protein source in breakfast cereals, bakery products, sausage casings and imitation dairy and meat products.

1.3 The current standard

Pre-market approval is necessary before a genetically modified (GM) food can enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment. Standard 1.5.2 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 of the Code.

Section 1.5.2—4 of Standard 1.5.2 also contains 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. Standard 1.2.1 provides that the requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer - see subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

Foods listed in subsections S26—3(2), (2A) 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 these subsections 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.

Subsection 1.1.1—10(8) of Standard 1.1.1 and general provisions states that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

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

The safety assessment of GMB151 is provided in Supporting Document 1 (SD1).

In conducting a safety assessment of food derived from GMB151, a number of criteria have been addressed, focusing on both the safety of the host soybean plant and the genetically modified soybean line GMB151, expressing the novel proteins. The safety of GMB151 included a full characterisation of the introduced gene sequences, biochemical, potential toxicity and potential allergenicity analyses of the novel Cry14Ab1 and HPPD-4 proteins and compositional analyses. A major consideration of the safety assessments was the evaluation of both the intended and any unintended changes, resulting from the genetic modification.

The assessment of GMB151 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 to apply for commercial cultivation of GMB151 in Australia or New Zealand. For cultivation in Australia, this would require assessment and approval by the Office of the Gene Technology Regulator. 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 and other information, food derived from soybean line GMB151 is considered to be as safe for human consumption as food derived from conventional soybean cultivars.

2.2 Risk management

2.2.1 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food derived from GMB151 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), (2A) 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 GMB151 does not have altered characteristics.

Products from GMB151 such as soy flour, protein concentrates and protein isolates can be used in a range of foods. These ingredients would contain novel protein and/or novel DNA and would require to be labelled as 'genetically modified'. Refined soybean oil from GMB151 would be exempt from the labelling statement where the effect of the refining process was to remove novel DNA or novel protein (see paragraph 1.5.2—4(1)(a)(i) of Standard 1.5.2).

The requirements for labelling as 'genetically modified' also differ depending on whether the GM food is an ingredient of the food for sale or not. For example, noodles made from soybean derived from GMB151, where the noodles are available for retail sale, would require the labelling statement.

However, FSANZ notes that GMB151 products may be used to manufacture a food that is not itself a food for sale, but is used as an ingredient in foods for retail sale or in food sold to a caterer (for example, soy flour made from GMB151 is used to make noodles, and the noodles are used as an ingredient in a mixed ready meal for sale). As such, the soy flour is not a GM food ingredient and is not subject to labelling requirements set out in section 1.5.2—4(1).

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-Committee¹ 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 A1196.

¹ Now known as the Implementation Subcommittee for Food Regulation

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.

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.

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 GMB151 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) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as varying Schedule 26 is a consequential change of maintaining a permitted schedule of GM foods. Additionally, permitting new GM foods is deregulatory as using the GM technology will be voluntary if the Application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status

quo is rejecting the application). This analysis considers permitting food derived from nematode-protected and herbicide-tolerant soybean line GMB151.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting food derived from GMB151. FSANZ is of the view that no other realistic food regulatory measures exist, however information received through the consultation process may result in FSANZ arriving at a different conclusion.

Costs and benefits of permitting food derived from GMB151

Foods derived from GMB151 would be permitted under the Code, allowing broader market access and increased choice in raw materials. For those food products containing novel DNA or novel protein from GMB151, required labelling would allow consumers wishing to avoid these products to do so.

Due to the voluntary nature of the permission, manufacturers and retailers would only engage with foods containing GMB151, where they believe a net benefit exists for them. Part of any cost savings to industry may be passed onto consumers.

There may be small and likely inconsequential costs of monitoring an extra food ingredient for regulators to ensure compliance with labelling requirements.

Approval would appear consistent with Australian and New Zealand obligations under WTO agreements and Free Trade Agreements to the extent that the product has been demonstrated to be safe.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting food derived from nematode-protected and herbicide-tolerant soybean line GMB151 most likely outweigh the associated costs.

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 A1196.

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 GMB151 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 GMB151 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 GMB151 have been submitted

Country	Agency	Type of approval sought	Status
United States of America	Environmental Protection Agency	Experimental use permit	Approved 2017
		Section 3 Seed Increase Registration	Submitted 2018
	Food and Drug Administration	Food approval	Submitted 2019
Canada	Health Canada	Food approval	Submitted 2019
	Canadian Food Inspection Agency	Feed approval and cultivation	Submitted 2019
Uruguay	Risk Management Commission (CGR)	Food and feed approval	Submitted 2019

Further other relevant matters are considered below.

2.4.2. Subsection 18(1)

FSANZ has also considered 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 GMB151 has been assessed based on the data requirements provided in the FSANZ [Application Handbook](#)² 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 GMB151 is considered as safe and wholesome as food derived from other commercial soybean 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 GMB151 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:

² www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx

- **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, 2009). Based on these principles, the risk analysis undertaken for GMB151 used the best scientific evidence available. The applicant submitted 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 producing foods. Soybean line GMB151 is a new food crop designed to provide growers with additional nematode protection for soybean 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 (2009) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003 2nd edition. Codex Alimentarius Commission, Rome. <http://www.fao.org/3/a1554e/a1554e00.htm>

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 A1196 – Food derived from derived from nematode-protected and herbicide-tolerant soybean line GMB151) 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]

Scott Crerar
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 A1196 – Food derived from nematode-protected and herbicide-tolerant soybean line GMB151) 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 7

- (q) nematode-protected and herbicide-tolerant soybean line GMB151

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.

The Authority accepted application A1196 which seeks approval for food derived from soybean line GMB151, genetically modified to be protected from parasitic nematodes and tolerant to HPPD-inhibitor herbicides. 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 soybean line GMB151.

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 A1196 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 soybean line GMB151, 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 (q) into item 7 in the table to subsection S26—3(4) in Schedule 26. The new paragraph refers to 'nematode-protected and herbicide-tolerant soybean line GMB151'. The effect of the variation is to permit the sale of food derived from that soybean line in accordance with the Code.