25 September 2020
[135-20]

Approval report – Application A1196

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

Food Standards Australia New Zealand (FSANZ) has assessed 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 permit the sale and use of food derived from a new genetically modified (GM) soybean line (GMB151). This soybean line has been genetically modified to be protected from parasitic nematodes and tolerant to HPPD-inhibitor herbicides such as isoxaflutole.

On 14 April 2020, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 9 submissions.

FSANZ approved the draft variation on 16 September 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 24 September 2020.

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

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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 (at Approval)

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 permit the sale and use of food derived from a new genetically modified (GM) soybean line (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 (non-GM) soybean cultivars.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 14 April 2020. A total of nine submissions were received, all of which FSANZ has had regard to (see Section 2.1 of this report for a summary of submissions made and FSANZ's responses to those submissions).

FSANZ has decided to approve the draft variation proposed following assessment without change. The draft variation amends Schedule 26 to include a reference to 'nematode-protected and herbicide-tolerant soybean line GMB151'. The effect of the draft variation will be to permit the sale and use 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. This application sought a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to permit the sale and use of food derived 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 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 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

FSANZ received a total of nine submissions. Submissions that supported the proposed draft variation were received from:

- Victorian Department of Health and Human Services and Victorian Department of Jobs, Precincts and Regions (VicHealth)
- New Zealand Ministry for Primary Industries (MPI)
- New Zealand Food and Grocery Council (NZFGC).

MPI requested some clarification on three specific issues, which have been addressed in the Summary of Issues (Table 1).

Submissions that opposed the draft variation were received from six private individuals. These individuals raised general concerns about GM foods including their safety, labelling and the presence of herbicides. These issue have been addressed in Table 1.

For reasons set out below, the following issues raised in submissions are not addressed in Table 1.

- Four of the submissions followed a similar theme, focusing on court cases in the United States regarding the herbicide glyphosate. GMB151 is not a glyphosate-tolerant crop and this issue therefore falls out of scope of this application.
- Another concern claimed that cultivation of GMB151 would encourage farmers to use of a “plethora” of herbicides, leading to an increase in accumulation of herbicides in the food. GMB151 has only been engineered for tolerance to HPPD-inhibitor herbicides. Therefore it is considered this issue falls outside the scope of this application.

However, as the issue of herbicide levels in food is common to all of the private individual submissions, information pertaining to this has been addressed in the Table 1.

Table 1: Summary of issues

	Issue	Raised by	FSANZ response
1	The deletion of the left border and 481 base pairs (bp) of the *P2x35S* enhanced promoter sequence (from cauliflower mosaic virus), which drives expression of the *hppdPf-4Pa* gene, was noted. Subsequent material in the assessment made it clear that the HPPD-4 protein was expressed, indicating that the promoter remained functional. It appears that the deletion was of no significance, but this is not stated in the assessment.	MPI	FSANZ notes reference to this deletion is provided in the Executive Summary of the SD1, however this could have been made clearer in the body of the safety assessment. Additional text has now been added to Section 3.4.3 in the SD1.
2	The open reading frame (ORF) analysis of the insertion identified a large number of ORFs coding for putative peptides of 3 amino acids or more. The application restricted further analysis of the putative peptides to those of 30 amino acids or more. Other GM food applications have chosen a much lower cut-off point (e.g. A1192, 8 amino acids). FSANZ is encouraged to seek standardisation of this component of the applications, with a clear rationale for the cut-off used.	MPI	Under the FSANZ Application Handbook (Guideline 3.5.1, Part B.1(d)) putative ORFs in the insert and junction region must be analysed for potential allergenicity and toxicity. The Handbook does not specify the minimum amino acid length for putative ORFs, nor does any scientific consensus on minimum length exist. FSANZ notes however that a length of 30 amino acids may be more relevant in the context of food safety, specifically potential allergenicity or toxicity. While standardising a minimum length would provide greater consistency between assessments, FSANZ notes a strong rationale for assessing the potential toxicity and allergenicity of putative ORFs does not exist in the scientific literature.
3	The assessments of acute toxicity carried out only considered a single species, at a single dose. Given the uncertainty around the mechanism of action of the Cry14Ab1 protein, a more detailed analysis of its potential acute mammalian toxicity would have provided greater assurance of the safety of this protein for human consumption. However, it is noted that *in silico* analyses did not identify any significant similarity with known allergens or toxins.	MPI	FSANZ notes there is no evidence that Cry proteins produced by *Bacillus thuringiensis* are harmful to humans. Cry proteins are known to have a very narrow range of target species and toxicity studies have confirmed that Cry proteins do not cause adverse effects in mammals. While the specific mode of action of Cry14Ab1 has not been fully elucidated, the general mode of action of nematocidal Cry proteins is consistent with that of insecticidal Cry proteins (Section 4.1 SD1).
	Action of the Cry14Ab1 protein - If the mechanism of how the protein works has not been determined, how could we know if it will not have negative health effect on humans?	CD	FSANZ's assessment demonstrated the Cry14Ab1 protein is heat labile at standard cooking temperatures and is fully degraded during processing. The protein also does not have any significant similarity to known allergens or toxins. The acute toxicity study provided additional confirmation that Cry14Ab1 is not toxic to mammals (Section 4.1.3 SD1). FSANZ notes the toxicity study was conducted in compliance with the relevant OECD test guideline[1].

[1] Test No. 420:Acute oral toxicity – fixed dose procedure; https://doi.org/10.1787/9789264070943-en

	Issue	Raised by	FSANZ response
4	Concerns were raised about safety, specifically whether sufficient testing was undertaken and the fact that animal feeding studies had not been done.	BA, CD	In Australia and New Zealand, GM foods require a premarket safety assessment and approval by FSANZ. The specific requirements for this assessment are outlined in the Application Handbook[2] (Guideline 3.5.1). The approach used by FSANZ and outlined in the Application Handbook is based on core concepts, principles and guidelines established by the Codex Alimentarius Commission (Codex 2009). The key focus in determining safety is the comparative assessment approach (OECD 1993; further information in Herman et al. 2009). Since 2003, the assessment approach developed by Codex has proven to be a robust approach for GM food safety assessments. The use of animals studies to support the safety assessment of GM foods, was considered in a workshop convened by FSANZ in 2007[3]. It was concluded that such studies generally do not contribute meaningful information to the GM food safety assessment. There were only limited circumstances where such studies may be informative, for example in the case of nutritional modification. Therefore, for most GM foods, feeding trials of any length are unlikely to contribute any further useful information to the safety assessment and are not warranted. There are also ethical concerns about the use of animals for feeding studies in the absence of any clearly identified compositional differences (Bartholomaeus et al. 2013; 2015; Coumoul et al. 2019). Consumers can be confident that GM foods assessed under Guideline 3.5.1 and approved for food use are as safe as their conventional (non-GM) counterparts
5	Concerns were raised about changes in nutrient composition following herbicide treatment.	CDW, BF, DF, RF	A comparison of the compositional data for untreated vs herbicide treated GMB151 (Section 5.3 SD1) showed herbicide treatment did not impact nutrient levels. Minor differences were seen on a per plant and per field trial site level, as would be expected. These differences are consistent with normal biological variability that exists in soybean, driven by environmental factors, as indicated by the different nutrient levels observed in the non-GM parental and reference cultivars.
6	Concerns there is insufficient data on the potential impact of unintended mutations from gene editing and transgenic engineering.	BA	In this application, the development of GMB151 involved the introduction of transgenic DNA. No gene editing techniques were involved. As part of the characterisation of GMB151, the entire genome was sequenced and compared to the parental control genome (Section 3.4 SD1). The only modification identified was the intended introduction of the transgenic DNA. There was no evidence of unintended changes to the GMB151 genome.

[2] www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx
[3] www.foodstandards.gov.au/consumer/gmfood/pages/roleofanimalfeedings3717.aspx

	Issue	Raised by	FSANZ response
7	Concerns that FSANZ did not rely on independent data sources for its assessments.	CDW, BF, DF, RF	FSANZ conducted its assessment as outlined in Issue 4 above. In addition to data submitted by the applicant, FSANZ also considered information from the scientific literature, general technical information, information from other assessment agencies, as well as from international bodies such as OECD or Codex. Studies (including raw data) supplied by the Applicant were independently assessed by FSANZ to ensure they are of sufficient quality for regulatory purposes and have been conducted in an appropriate manner.
8	General concerns about the presence of herbicide residues in GM foods and health impacts on consumers.	BA, CD, CDW, BF, DF, RF	Food to be sold in Australia must not contain levels of agricultural chemical residues above the maximum residue limits (MRLs). MRLs are listed in Schedules 20 and 21 of the Australia New Zealand Food Standards Code[4]. For food sold in New Zealand, MRLs are established by the Ministry for Primary Industries. In order for MRLs to be established,, an assessment is made to consider consumer dietary exposure estimates to pesticides against health based guidance values. MRLs are established for all foods, regardless of whether a product or commodity is GM or non-GM. For further details about MRLs please visit the FSANZ website *Chemicals in Food*[5] or the NZ MPI website *Maximum residue levels (MRLs) for agricultural compounds*[6]. Further questions related to toxicity of pesticides can also be addressed to the Australian Pesticide and Veterinary Medicine Authority[7] in Australia and the Environmental Protection Authority[8] in New Zealand.
9	Concerns about GE/GMO plants and food ingredients going into the Australian and NZ food supply, unlabelled, and undermining consumer "right to know" and traceability.	BA	Approved GM foods are subject to mandatory labelling requirements under the Code. Food derived from GMB151 will be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein, as outlined and discussed in section 2.3.1 of this Report.

[4] www.foodstandards.gov.au/code/Pages/default.aspx
[5] www.foodstandards.gov.au/consumer/chemicals/maxresidue/Pages/default.aspx
[6] www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/maximum-residue-levels-for-agricultural-compounds/
[7] apvma.gov.au
[8] www.epa.govt.nz

2.2 Safety assessment

The safety assessment of food derived from GMB151 is provided in Supporting Document 1 (SD1) at Approval.

In conducting the safety assessment, a number of criteria were addressed, including 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. This assessment considered both the intended and any unintended changes resulting from the genetic modification.

The safety 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 were identified as a result of the safety assessment.

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 non-GM soybean cultivars.

The SD1 at Approval has been modified to clarify information in Section 3.4.3.

2.3 Risk management

2.3.1 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food derived from GMB151 will 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 will contain novel protein and/or novel DNA and will be required to be labelled as 'genetically modified'. Processing during production means novel protein and novel DNA are not likely to be present in the oil; in the absence of novel protein and novel DNA, refined oil from soybean line GMB151 will be exempt from labelling under paragraph 4(1)(c) 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).

2.3.2 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-Committee[9] 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.

2.4 Risk communication

2.4.1 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.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission on this application was considered by FSANZ. All comments are valued and contribute to the rigour of the safety assessment.

Documents relating to Application A1196, including submissions received, are available on the FSANZ website.

2.4.2 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.

[9] Now known as the Implementation Subcommittee for Food Regulation

2.5 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:

2.5.1 Section 29

2.5.1.1 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.

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 will outweigh the associated costs.

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 A1196.

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 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.

2.5.2. Subsection 18(1)

FSANZ has also considered 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 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 as food derived from other commercially available non-GM and GM soybean 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 GMB151 would be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see Section 2.3.1).

2.5.2.3 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.

2.5.3 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, 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 References

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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

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Ladics GS (2008) Current codex guidelines for assessment of potential protein allergenicity. Food Chem Toxicol 46(S10):S20-3

Ladics GS (2019) Assessment of the potential allergenicity of genetically-engineered food crops. J Immunotoxicol 16(1):43-53

OECD (1993) Safety evaluation of foods derived by modern biotechnology: Concepts and principles. Organisation for Economic Co-operation and Development, Paris.

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 A1196 – Food derived from nematode-protected and herbicide-tolerant soybean line GMB151) 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 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 clause 3 of the variation.

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 – 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 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 sunsetting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved the draft variation to permit the sale and use of food derived from genetically modified soybean line GMB151, genetically modified to be protected from parasitic nematodes and tolerant to HPPD-inhibitor herbicides. The sale and use of food derived from soybean line GMB151 would be in accordance with the Code.

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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report.

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] amends Schedule 26 by inserting, in alphabetical order, 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 and use of food derived from that soybean line in accordance with the Code.