

**7 January 2025**  
**324-25**

## **Call for submissions – Application A1310**

### **Food derived from insect-protected soybean line MON94637**

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Bayer CropScience Pty Ltd. to amend the Australia New Zealand Food Standards Code to permit the sale and use of food derived from a new food produced using gene technology: soybean line MON94637. This soybean line has been genetically modified for protection against insect pests. A draft food regulatory measure has been prepared. 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.

Submissions on this application need to be made through the [Consultation Hub](https://consultations.foodstandards.gov.au/) (<https://consultations.foodstandards.gov.au/>).

All submissions on applications and proposals will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

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 [Making a submission](#).

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

### **DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 18 February 2025**

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.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#). Questions about making a submission or application and proposal processes can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand  
PO Box 5423  
KINGSTON ACT 2604  
AUSTRALIA  
Tel +61 2 6228 8226

Food Standards Australia New Zealand  
PO Box 10559  
WELLINGTON 6140  
NEW ZEALAND  
Tel +64 4 978 5630

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### Supporting document

The following document which informed the assessment of this application is available on the [A1310 page](#)<sup>1</sup> on the FSANZ website:

SD1      Safety Assessment Report

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<sup>1</sup> <https://www.foodstandards.gov.au/food-standards-code/applications/a1310-food-derived-insect-protected-soybean-line-mon94637>

## Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Bayer CropScience Pty Ltd to request 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 food produced using gene technology (GM food): soybean line MON94637. Soybean line MON94637 has been genetically modified (GM) for protection against lepidopteran insect pests.

A safety assessment is a critical part of the assessment approval process for all GM food applications. The completed safety assessment for soybean line MON94637 is in Supporting Document 1. The assessment found no potential public health and safety concerns. Based on the data provided by the applicant and other information, food derived from soybean line MON94637 is considered to be as safe for human consumption as food derived from conventional non-GM soybean varieties.

If approved, food derived from soybean line MON94637 may enter the Australian and New Zealand food supply as imported food products. These may include oil, milk, flour, meal, protein isolates and processed products.

If approved, existing labelling requirements for GM food would apply to food derived from soybean line MON94637 in accordance with the Code.

For reasons set out above and in the assessment summary, FSANZ has prepared a draft variation to amend Schedule 26 of the Code to insert a new paragraph (t) in item 7 of the table to subsection S26—3(4) containing a reference to ‘insect-protected soybean line MON94637’ to permit the sale and use of food derived from soybean line MON94637. If approved, the effect of the draft variation would be to permit the sale and use of food derived from this soybean line in accordance with the Code.

FSANZ seeks submissions on the draft variation.

# 1 Introduction

## 1.1 The Applicant

Bayer CropScience Pty Ltd is a technology provider to a number of sectors including the agriculture sector.

## 1.2 The Application

Application A1310 was submitted on 25 July 2024. It seeks an amendment to the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): soybean line MON94637. This soybean line has been genetically modified for protection against lepidopteran insect pests.

Protection against lepidopteran insect pests is conferred by the expression of *cry1A.2* and *cry1B.2* genes encoding two novel insecticidal proteins: Cry1A.2 and Cry1B.2, respectively. Cry1A.2 and Cry1B.2 are chimeric proteins comprised of multiple domains from different Cry proteins derived from the soil bacterium *Bacillus thuringiensis*. Food Standards Australia New Zealand (FSANZ) has assessed numerous previous applications for crops containing Cry proteins derived from *B. thuringiensis*. However, this is the first time FSANZ has assessed the Cry1A.2 and Cry1B.2 proteins.

If approved, food derived from soybean line MON94637 may enter the Australian and New Zealand food supply as imported food products. These may include oil, milk, flour, meal, protein isolates and processed products. Food from soybean line MON94637 containing viable seeds would require prior assessment and approval by the Gene Technology Regulator (GTR)<sup>2</sup> in Australia and the Environmental Protection Authority (EPA)<sup>3</sup> in New Zealand.

## 1.3 The current standard

### *Pre-market approval*

Standard 1.1.1 of the Code provides that, unless expressly permitted by the Code, a food for sale cannot be, or have as an ingredient or component, a GM food.<sup>4</sup> Standard 1.1.2 defines what is a 'food produced using gene technology' (referred to generally as a 'GM food' in this report) for this purpose.<sup>5</sup>

The above in effect requires pre-market approval of a GM food before it 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 sale of a food that is, or has as an ingredient, a GM food. Permitted GM foods are listed in Schedule 26 of the Code. Standard 1.5.2 also provides a GM food that is permitted for use as a food additive by Standard 1.3.1 or as a processing aid by Standard 1.3.3 is also a permitted GM food for the purposes of Standard 1.5.2.

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<sup>2</sup> The Office of the Gene Technology Regulator (OGTR) provides administrative support to the Gene Technology Regulator in the performance of functions under the *Gene Technology Act 2000*.

<sup>3</sup> The EPA implements and enforces the *Hazardous Substances and New Organisms (HSNO) Act 1996*.

<sup>4</sup> See paragraphs 1.1.1—10(5)(c) and 1.1.1—10(6)(g)

<sup>5</sup> See definition in subsection 1.1.2—2(3).

## Labelling

Standard 1.1.1 requires that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Section 1.5.2—4 requires a food for sale that consists of, or has as an ingredient, a food that is a *genetically modified food* to be labelled as 'genetically modified'.<sup>6</sup>

A genetically modified food is a GM food that:

- contains novel DNA or novel protein; or
- is listed in subsections S26—3(2), (2A) and (3) (i.e. regardless of the presence of novel DNA or novel protein in the foods). The foods listed in these subsections 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.

Section 1.5.2—4 also provides that its labelling requirements do not apply if the genetically modified food:

- has been highly refined (other than food that has an altered characteristic), 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 and no novel DNA or novel protein from the substance remains present in the food for sale;
- is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%); or
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient; or
- is intended for immediate consumption and is prepared and sold from food premises and vending vehicles, including restaurants, take away outlets, caterers, or self-catering institutions.

The labelling requirements imposed by section 1.5.2—4 apply to the following in accordance with Standard 1.2.1:

- a food for retail sale. Food for retail sale may include food that is not required by the Code to bear a label and is not in a package. In this case, subsections 1.2.1—9(2) and (3) require labelling information in section 1.5.2—4 to accompany the food or be displayed in connection with the display of the food; or
- a food sold to a caterer. Food sold to a caterer may include food that is not required by the Code to bear a label and is not in a package. In this case, section 1.2.1—13 and paragraph 1.2.1—15(f) require information in section 1.5.2—4 to be provided to the caterer with the 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 *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure

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<sup>6</sup> Subsection 1.5.2—4(5) defines *genetically modified food* to mean 'a \*food produced using gene technology that  
a) contains novel DNA or novel protein; or  
b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section' (that being section 1.5.2—4).

- 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 soybean line MON94637 is provided in Supporting Document 1 (SD1) and included the following key elements:

- a characterisation of the transferred genetic material, its origin, function, and stability in the soybean genome
- characterisation of novel nucleic acids and protein in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes
- assessment of the potential for any newly expressed protein to be either allergenic or toxic in humans.

In conducting the safety assessment, FSANZ had regard to information from a variety of sources including, but not limited to, a data package provided by the applicant (application and study reports), the scientific literature and other applications.

The assessment of soybean line MON94637 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 soybean line MON94637, or any risks to animals that may consume feed derived from soybean line MON94637. Permission to cultivate soybean line MON94637 or to import viable seeds into Australia or New Zealand would require separate regulatory assessment and approval by the GTR in Australia and by the EPA in New Zealand.

No potential public health and safety concerns have been identified.

Based on the data provided in the present application and other available information, food derived from soybean line MON94637 is considered to be as safe for human consumption as food derived from non-GM soybean varieties.

## **2.2 Risk management**

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code to permit the sale and use of food derived from soybean line MON94637. If approved, the effect of the draft variation would be to permit the sale and use of food derived from this soybean line in accordance with the Code.

## 2.2.1 Regulatory approval

Soybean line MON94637 is a GM food for Code purposes as it is derived from ‘an organism which has been modified by gene technology’. FSANZ is proposing to list soybean line MON94637 in the table to subsection S26—3(4). If approved, the proposed amendment would provide permission for the sale and use of food derived from soybean line MON94637 as a GM food in accordance with the Code.

## 2.2.2 Labelling

### 2.2.2.1 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 for sale derived from a GM food, such as soybean line MON94637, would be required to be labelled as ‘genetically modified’ if, among other things, the GM food:

- contains novel DNA or novel protein; or
- is listed in subsection S26—3(2), (2A) or (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 soybean line MON94637 does not have altered characteristics (see sections 5.3 and 6 of SD1).

Refined products from soybean line MON94637, such as soybean oil, are unlikely to contain any novel DNA or novel protein and would be unlikely to require labelling as ‘genetically modified’.

Products derived from soybean line MON94637, such as soy milk, flour, meal and protein isolates would likely contain novel DNA or novel protein, and if so, would require labelling as ‘genetically modified’.

Section 1.5.2—4 of the Code generally requires a food for sale that consists of a genetically modified food or has a genetically modified food as an ingredient, to be labelled as ‘genetically modified’, unless one of the exemptions listed in that section applies. Where required, the label statement ‘genetically modified’ must be made in conjunction with the name of the genetically modified food (subsection 1.5.2—4(2)). If the genetically modified food is present in the food for sale as an ingredient, food additive or processing aid, then the ‘genetically modified’ statement may be included in the statement of ingredients (subsection 1.5.2—4(3)).

## 2.2.3 Detection methodology

An Expert Advisory Group (EAG) comprising laboratory personnel and representatives of Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee’s Implementation Sub-Committee<sup>7</sup> to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food produced using gene technology (GM applications).

The EAG indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR<sup>8</sup>-based detection method. This sequence information was supplied by the applicant for A1310.

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<sup>7</sup> Now known as the Implementation Subcommittee for Food Regulation.

<sup>8</sup> Polymerase Chain Reaction.

## **2.3 Risk communication**

### **2.3.1 Consultation**

Consultation is a key part of FSANZ's standards development process.

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

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation.

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

The applicant, 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 not substantially the same as existing 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 soybean line MON94637 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 is 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**

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA).<sup>9</sup> Impact analysis is no longer required to be finalised with OIA. Prior to these changes, OIA advised FSANZ a Regulatory Impact Statement (RIS) was not required for applications relating to GM foods (OIA Reference: OIA23-06225). This is because applications relating to permitting use of GM foods determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the application is approved. Under the new approach, FSANZ's assessment is a RIS is not required for this application.

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<sup>9</sup> [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](https://www.pmc.gov.au/regulatory-impact-analysis-guide-for-ministers-meetings-and-national-standard-setting-bodies)



FSANZ, however, has considered 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 or 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 the sale and use of food derived from soybean line MON94637.

Consideration of costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects considered cannot easily be assigned a dollar value. The assessment seeks to highlight the potential positives and negatives of moving away from the status quo by permitting the sale and use of food derived from soybean line MON94637.

FSANZ's conclusions regarding costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

#### *Costs and benefits of permitting sale and use of food derived from soybean line MON94637*

If approved, food derived from soybean line MON94637 may enter the Australian and New Zealand food supply as imported food products. These may include soybean oil, milk, flour, meal, protein isolates and processed products.

The sale and use of foods derived from soybean line MON94637 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 soybean line MON94637, labelling would be required to assist consumers wishing to avoid these products.

Due to the voluntary nature of the permission, manufacturers and retailers would only engage with foods derived from soybean line MON94637 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 GM food ingredient for regulators to ensure compliance with labelling requirements.

#### *Conclusions from cost benefit considerations*

FSANZ's assessment is the direct and indirect benefits that would arise from permitting sale and use of food derived from soybean line MON94637 most likely outweigh 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 a food regulatory measure developed or varied as a result of the application.

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

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

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

The applicant has submitted applications for regulatory approval of soybean line MON94637

to other countries, as listed in Table 1.

Cultivation in Australia or New Zealand would require independent assessment and approval by the GTR in Australia and the EPA in New Zealand.

**Table 1. List of countries to whom applications for regulatory approval of MON94637 have been submitted.**

Country	Authority	Type of approval sought	Status
United States	Food and Drug Administration (FDA)	Food and Feed	Approved
Canada	Canadian Food Inspection Agency (CFIA)	Food and Environment	Approved
	Health Canada	Food	Approved
Brazil	Comissão Técnica Nacional de Biossegurança (CTNBio)	Cultivation	Approved
Uruguay	Gabinete Nacional de Bioseguridad (GNBio)	Cultivation	Submitted
European Union	The European Food Safety Authority (EFSA)	Food and Feed	Submitted
China	Ministry of Agriculture and Rural Affairs (MARA)	Food and Feed	Submitted
Korea	Ministry of Food and Drug Safety (MFDS)	Food	Submitted
	Rural Development Administration	Feed	Submitted
Taiwan	Taiwan Food and Drug Administration (TFDA)	Food	Submitted
	Ministry of Agriculture (MOA)	Feed	Submitted
Japan	Ministry of Health, Labor and Welfare (MHLW)	Food	Submitted
	Ministry of Agriculture, Forestry and Fisheries (MAFF)	Feed	Submitted

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**

FSANZ's assessment did not identify any public health and safety concerns with food derived from soybean line MON94637. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is food derived from soybean line MON94637 is as safe for human consumption as food derived from other conventional non-GM soybean varieties.

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

Existing labelling requirements for GM food will apply to food derived from soybean line MON94637 in accordance with the Code to enable informed consumer choice (see section 2.2.2).

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

The provision of DNA sequence information by the applicant (section 2.2.3) satisfies this objective.

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

FSANZ 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 by FSANZ for soybean line MON94637 used the best scientific evidence available. The applicant submitted a comprehensive dossier of quality-assured raw experimental data. In addition to information supplied by the applicant, other available resource material including published scientific literature and general technical information was used by FSANZ 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 product developers and a widening of the technological base for producing foods. Soybean line MON94637 is a new food crop designed to provide growers with an additional control option for lepidopteran insect pests.

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

Issues related to consumer information and safety are considered in sections 2.1, 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 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. 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 A1310 – Food derived from insect-protected soybean line MON94637) 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]

[Insert name and position of Delegate]

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 A1310 – Food derived from insect-protected soybean line MON94637) 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**

**Schedule 26—Food produced using gene technology**

**[1] Subsection S26—3(4) (table item 7, column headed “Food derived from:”)**

Insert:

(t) insect-protected soybean line MON94637

# Attachment B – Draft Explanatory Statement

## DRAFT EXPLANATORY STATEMENT

*Food Standards Australia New Zealand Act 1991*

### ***Food Standards (Application A1310 – Food derived from insect-protected soybean line MON94637) Variation***

#### **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 A1310 which seeks to amend the Code to permit the sale and use of food derived from a new food produced using gene technology (GM food) – soybean line MON94637. Soybean line MON94637 has been genetically modified for protection against lepidopteran insect pests. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1310 – Food derived from insect-protected soybean line MON94637) Variation*.

#### **2. Variation will be a legislative instrument**

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation ([www.legislation.gov.au](http://www.legislation.gov.au)).

If approved, this instrument would not be subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Minister's Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

### 3. Purpose

The Authority has prepared a draft variation amending the table to subsection S26—3(4) in Schedule 26 of the Code to permit the sale and use of food derived from soybean line MON94637, in accordance with the Code. Soybean line MON94637 has been genetically modified for protection against lepidopteran insect pests.

### 4. Documents incorporated by reference

This draft variation does not incorporate any documents by reference.

### 5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1310 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-week period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA).<sup>10</sup> Impact analysis is no longer required to be finalised with the OIA. Prior to those changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for applications relating to GM foods, updated OIA reference: **OIA23-06225**. This is because applications relating to permitting the use of GM foods that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation relating to the application is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

### 6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

### 7. Variation

Clause 1 of the draft variation provides that the name of the variation is the *Food Standards (Application A1310 – Food derived from insect-protected soybean line MON94637) Variation*.

Clause 2 of the draft variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the draft variation provides that the variation will commence on the date of gazettal of the instrument.

Item [1] of the Schedule to the draft variation would amend Schedule 26 by inserting, in alphabetical order, new paragraph '(t)' into the column headed '*Food derived from:*' for item 7 of the table to subsection S26—3(4) of the Code. Item 7 of this table is headed 'Soybean'.

The new paragraph (t) refers to 'insect-protected soybean line MON94637'.

If approved, the draft variation would permit the sale and use of food derived from soybean line MON94637, in accordance with the Code.

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<sup>10</sup> [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](https://www.pmc.gov.au/regulatory-impact-analysis-guide-for-ministers-meetings-and-national-standard-setting-bodies)