18 June 2025
345-25

Approval report – Application A1323

Food derived from insect-protected soybean line COR23134

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Corteva Agriscience Australia 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 COR23134. This soybean line has been genetically modified for protection from insect pests.

On 4 March 2025, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received one submission.

FSANZ approved the draft variation on 4 June 2025. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 18 June 2025.

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

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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Supporting document

The following document which informed the assessment of this application is available on the A1323 page on the FSANZ website[2]:

SD1 Supporting Document 1 – Safety assessment report

[2] https://www.foodstandards.gov.au/food-standards-code/applications/a1323-food-derived-insect-protected-soybean-line-cor23134

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from Corteva Agriscience Australia Proprietary Limited seeking a variation of 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 COR23134. Soybean line COR23134 has been genetically modified (GM) for protection from lepidopteran insect pests.

As stated in section 18 of the *Food Standards Australia New Zealand Act 1991*, the primary objective of FSANZ in developing or varying a food regulatory measure is the protection of public health and safety. Accordingly, a safety assessment is a critical part of the assessment and approval process for all GM food applications.

The safety assessment for soybean line COR23134 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 COR23134 is as safe for human consumption as food derived from conventional non-GM soybean varieties.

Existing labelling requirements for GM food will apply to food derived from soybean line COR23134 in accordance with the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 4 March 2025. One submission was received in the six-week consultation period and that submission supported the draft variation.

For reasons set out in this report, FSANZ has decided to approve the draft variation proposed at the call for submissions without change. The approved draft variation will amend Schedule 26 of the Code to include a new paragraph (u) for item 7 in the table to subsection S26—3(4) containing a reference to ‘insect-protected soybean line COR23134’. The effect of the approved draft variation will be to permit the sale and use of food derived from this soybean line in accordance with the Code.

1 Introduction

1.1 The applicant

Corteva Agriscience Australia Proprietary Limited is a member of the Corteva Agriscience group, a global agriculture company.

1.2 The application

Application A1323 was submitted on 6 December 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 COR23134. This soybean line has been genetically modified (GM) for protection from lepidopteran insect pests. COR23134 expresses four novel substances, summarised in Table 1.

Table 1. Novel substances expressed in COR23134

Protein	Gene	Donor organism	Function	Previously assessed by FSANZ?
Cry1B.34.1	*cry1B.34.1*	*Bacillus thuringiensis*	Confers protection from lepidopteran insect pests	The full-length version of this protein, Cry1B.34, has been previously assessed (A1281)
Cry1B.61.1	*cry1B.61.1*	*Bacillus thuringiensis*	Confers protection from lepidopteran insect pests	No
IPD083Cb	*ipd083Cb*	*Adiantum trapeziforme* var. *braziliense*	Confers protection from lepidopteran insect pests	No
GM-HRA	*gm-hra_1*	*Glycine max*	Selectable marker	Yes (A1018)

1.2.1 Safety assessment sharing with Health Canada

This is the fifth GM application assessed under the FSANZ-Health Canada Shared Assessment Process.[3]

Extensive work undertaken in the early stages of the collaboration confirmed the compatibility of FSANZ and Health Canada's safety assessment approaches, both in terms of how safety assessments are conducted and the conclusions reached.[4] Both agencies also adhere to internationally agreed principles and guidelines for the conduct of GM food safety assessments developed by the Codex *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology (Codex, 2009). This provides a strong basis for safety assessment sharing between the two agencies.

The goal of safety assessment sharing is to establish a system where a safety assessment is jointly prepared and meets the separate requirements of both agencies, with each undertaking their own separate and independent approval process.

[3] See https://www.foodstandards.gov.au/consumer/gmfood/health-canada-fsanz-shared-assessment-process for more information.
[4] https://www.foodstandards.gov.au/consumer/gmfood/health-canada-fsanz-shared-assessment-process/pilot

For soybean line COR23134 (the current application), the joint food safety assessment was prepared by Health Canada, then provided to FSANZ for review and to inform the preparation of Supporting Document 1.

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.[5] 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.[6]

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.

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'.[7]

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

[5] See paragraphs 1.1.1—10(5)(c) and 1.1.1—10(6)(g).
[6] See definition in subsection 1.1.2—2(3).
[7] 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*).

- 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%)
- 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. In the case where a food for retail sale is not required by the Code to bear a label and is not in a package, 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. In the case where a food sold to a caterer is not required by the Code to bear a label, 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
- 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

For reasons set out in this report, the draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 4 March 2025. The consultation period was six weeks.

One submission was received during the call for submissions period - from New Zealand Food Safety. The submission supported the proposed draft variation to Schedule 26 and did not raise any issues.

2.2 Safety assessment

The safety assessment of soybean line COR23134 is provided in Supporting Document 1 (SD1) and includes 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 COR23134 was restricted to human food safety and nutritional issues consistent with FSANZ's statutory remit. This assessment therefore does not address any risks to the environment that may occur as the result of growing soybean line COR23134, or any risks to animals that may consume feed derived from soybean line COR23134. Permission to cultivate soybean line COR23134 or to import viable seeds into Australia or New Zealand would require separate regulatory assessment and approval by the Gene Technology Regulator (GTR)[8] in Australia and the Environmental Protection Authority (EPA)[9] in New Zealand.

No potential public health and safety concerns have been identified.

Based on the data provided in the application and other available information, food derived from soybean line COR23134 is as safe for human consumption as food derived from non-GM soybean varieties.

2.3 Risk management

Following assessment, FSANZ prepared a draft variation of the Code and called for submissions on that draft variation.

The risk management options available to FSANZ following the call for submissions were to:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

Following the call for submissions and having regard to the submission received and for the reasons set out in this report, FSANZ has decided to approve the draft variation proposed following assessment without change (see Attachment A).

[8] 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*.
[9] The EPA implements and enforces the *Hazardous Substances and New Organisms* (HSNO) *Act 1996*.

Risk management considerations for this application relating to the regulatory approval, labelling and detection methodology are discussed below.

2.3.1 Regulatory approval

Soybean line COR23134 is a GM food for Code purposes as it is developed from 'an organism which has been modified by gene technology'[10]. The approved draft variation lists soybean line COR23134 in the table to subsection S26—3(4). This amendment will effectively provide permission for the sale and use of food derived from soybean line COR23134 as a GM food in accordance with the Code.

Subject to and in accordance with the draft variation, food derived from soybean line COR23134 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.

Cultivation of soybean line COR23134 would require separate prior assessment and approval by the GTR in Australia and the EPA in New Zealand.

2.3.2 Labelling

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 COR23134 will require labelling 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 COR23134 does not have altered characteristics (see sections 5.3 and 6 of SD1).

Refined products from soybean line COR23134, such as soybean oil, are unlikely to contain any novel DNA or novel protein and will be unlikely to require labelling as 'genetically modified'.

Products derived from soybean line COR23134, such as soy milk, flour, meal and protein isolates will likely contain novel DNA or novel protein, and if so, will 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 subsection apply. Where required, the label statement 'genetically modified' must be made in conjunction with the name of the GM food (subsection 1.5.2—4(2)). If the GM 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)).

2.3.3 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

[10] ***Food produced using gene technology*** is defined in subsection 1.1.2—2(3) of the Code as 'a food which has been derived or developed from an organism which has been modified by gene technology'.

Committee's Implementation Sub-Committee[11] 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 for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR[12]-based detection method. This sequence information was supplied by the applicant for A1323.

2.4 Risk communication

2.4.1 Consultation

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

The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions were invited on a draft variation released for public comment between 4 March 2025 and 15 April 2025. The call for submissions was notified via the FSANZ Notification Circular, media release and Food Standards News. Subscribers and interested parties were also notified.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on applications to amend the Code. All submissions are considered by FSANZ as part of the decision-making process. All comments are valued and contribute to the rigour of our assessment.

Documents relating to A1323, including the submission received, are available on the FSANZ website[13].

The draft variation was considered for approval by the FSANZ Board having regard to the submission made during the call for submissions period.

2.5 FSANZ Act assessment requirements

When assessing this application, and in the subsequent development and approval 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

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA).[14] Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for the applications relating to GM foods. 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 concerned is approved. Under the new approach, FSANZ's assessment is that a RIS is not

[11] Now known as the Implementation Subcommittee for Food Regulation.
[12] Polymerase Chain Reaction.
[13] https://www.foodstandards.gov.au/food-standards-code/applications/a1323-food-derived-insect-protected-soybean-line-cor23134
[14] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

required for this application.

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 the sale and use of food derived from insect-protected soybean line COR23134.

The consideration of the 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 that were considered cannot easily be assigned a dollar value. Rather, 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 insect-protected soybean line COR23134.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below.

Consideration of costs and benefits of permitting the sale and use of food derived from insect-protected soybean line COR23134

Food derived from soybean line COR23134 may enter the Australian and New Zealand food supply as imported food products. These may include soybean oil, soy milk, flour, meal and protein isolates.

The sale and use of foods derived from soybean line COR23134 will be permitted under the Code, allowing broader market access and increased choice in raw materials. Due to the voluntary nature of the permission, manufacturers and retailers will only engage with foods derived from soybean line COR23134 where they believe a net benefit exists for them. Part of any cost savings experienced by the food industry may be passed onto consumers.

For those food products containing novel DNA or novel protein from soybean line COR23134, labelling is required to assist consumers wishing to avoid these products.

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

Conclusions from cost benefit considerations

FSANZ's assessment at the call for submissions stage was that the direct and indirect benefits that would arise from permitting the sale and use of food derived from soybean line COR23134 most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

2.5.1.2 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.

2.5.1.3 Any relevant New Zealand standards

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

2.5.1.4 Any other relevant matters

The applicant has submitted applications for regulatory approval of soybean line COR23134 to other countries, as listed in Table 2.

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

Table 2. List of countries to whom applications for regulatory approval of COR23134 have been submitted.

Country	Authority	Type of approval sought	Status
Argentina	National Advisory Commission on Agricultural Biotechnology (CONABIA)	Cultivation	Pending
Canada	Health Canada (HC)	Food	Submitted
Columbia	National Institute for Food and Drug Surveillance (INVIMA)	Food	Pending
Japan	Ministry of Agriculture, Forestry and Fisheries (MAFF)	Feed	Submitted
United States	Food and Drug Administration	Cultivation	Approved

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

FSANZ's assessment did not identify any public health and safety concerns with food derived from soybean line COR23134. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from soybean line COR23134 is as safe for human consumption as food derived from other conventional non-GM soybean varieties.

2.5.2.2 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 COR23134 in accordance with the Code to enable informed consumer choice (see section 2.3.2).

2.5.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this application relevant to 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 by FSANZ for soybean line COR23134 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 COR23134 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 2.2 and 2.3 above.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

No specific policy guidelines have been developed.

3 Draft variation

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

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

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

Food Standards (Application A1323 – Food derived from insect-protected soybean line COR23134) 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]

Matthew O'Mullane
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 A1323 – Food derived from insect-protected soybean line COR23134) 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:

(u) insect-protected soybean line COR23134

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1323 – Food derived from insect-protected soybean line COR23134) 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 A1323 which sought 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 COR23134. Soybean line COR23134 has been genetically modified for protection from lepidopteran insect pests. The Authority considered the Application in accordance with Division 1 of Part 3 and approved a draft variation - the *Food Standards (Application A1323 – Food derived from insect-protected soybean line COR23134) Variation* (the approved draft variation).

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunsetting 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 sunsetting 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 sunsetting 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 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 approved 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 COR23134, in accordance with the Code. Soybean line COR23134 has been genetically modified for protection from lepidopteran insect pests.

4. Documents incorporated by reference

The approved 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 A1323 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 4 March 2025 for a six-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA).[15] Impact analysis is no longer required to be finalised with the OIA. Prior to these 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 the use of the GM food will be voluntary if the draft variation related 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

This instrument is 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

References to 'the variation' in this section are references to 'the approved draft variation'.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1323 – Food derived from insect-protected soybean line COR23134) Variation*.

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

[15] https://oia.pmc.gov.au/resources/guidance-impact-analysis/regulatory-impact-analysis-guide-ministers-meetings-and-national

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

Item [1] of the Schedule to the variation amends Schedule 26 of the Code by inserting, in alphabetical order, new paragraph '(u)' 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 (u) refers to 'insect-protected soybean line COR23134'.

The effect of the variation is to permit the sale and use of food derived from soybean line COR23134 in accordance with the Code.