26 March 2025
334-25

Approval report – Application A1302

Food derived from insect-protected corn line MZIR260

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Syngenta Pty Ltd seeking 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: corn line MZIR260. This corn line has been genetically modified for protection against insect pests.

On 22 October 2024, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received one submission.

FSANZ approved the draft variation on 12 March 2025. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 26 March 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 A1302 webpage on the FSANZ website[2]:

SD1 Supporting Document 1 – Safety assessment report

[2] https://www.foodstandards.gov.au/food-standards-code/applications/application-a1302-food-derived-insect-protected-corn-line-mzir260

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from Syngenta Australia Pty Ltd. seeking 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): corn line MZIR260. Corn line MZIR260 has been genetically modified (GM) for protection against lepidopteran insect pests.

As stated in section 18 of the *Food Standards Australia New Zealand Act 1991*, a 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 approval process for all GM food applications.

The safety assessment of corn line MZIR260 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 corn line MZIR260 is considered to be as safe for human consumption as food derived from conventional non-GM corn cultivars.

Existing labelling requirements for GM food will apply to food derived from corn line MZIR260 in accordance with the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 22 October 2024. One submission was received in the six-week consultation period. FSANZ has had regard to this submission.

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 (zl) for item 2 in the table to subsection S26—3(4) containing a reference to ‘insect-protected corn line MZIR260’. The effect of the approved draft variation will be to permit the sale and use of food derived from this corn line in accordance with the Code.

1 Introduction

1.1 The applicant

Syngenta Australia Pty Ltd is a member of the Syngenta group, a global agriculture company.

1.2 The application

Application A1302 was submitted on 8 May 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): corn line MZIR260. This corn line has been genetically modified for protection against lepidopteran insect pests.

Protection against lepidopteran insect pests is conferred by the expression of the *eCry1Gb.1Ig-03* gene encoding the eCry1Gb.1Ig insecticidal protein. The *eCry1Gb.1Ig-03* gene is composed of two DNA sequences derived from the following *Bacillus thuringiensis* genes: (1) the *cry1Gb* gene; and (2) the *cry1Ig* gene. Food Standards Australian New Zealand (FSANZ) has assessed numerous previous applications for crops containing Cry proteins derived from *B. thuringiensis*, but this is the first time FSANZ has assessed the eCry1Gb.1Ig protein.

MZIR260 also expresses the phosphomannose isomerase (PMI) protein from *Escherichia coli* strain K-12 as a selectable marker. The PMI protein has been assessed previously by FSANZ.

1.2.1 Safety assessment sharing with Health Canada

This is the fourth GM application assessed under the joint safety assessment sharing arrangement with Health Canada.

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. 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.

For corn line MZIR260 (the current application), the joint food safety assessment was prepared by FSANZ (SD1) and then provided to Health Canada for review and use as part of their approval process.

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.[3] 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.[4]

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 that 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'.[5] 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 requirement does 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

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

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) requires 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

FSANZ called for submissions on a proposed draft variation to the Code on 22 October 2024. The consultation period was six weeks.

One submission was received. The submission, from New Zealand Food Safety (NZFS), supported the proposed draft variation to Schedule 26 and did not raise any issues.

2.2 Safety assessment

The safety assessment of corn line MZIR260 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 corn 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 considered 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 previous applications.

The assessment of corn line MZIR260 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 corn line MZIR260, or any risks to animals that may consume feed derived from corn line MZIR260. The importation of viable seeds or the cultivation of corn line MZIR260 in Australia or New Zealand would require separate regulatory assessment and approval by the Gene Technology Regulator (GTR)[6] in Australia and by the Environmental Protection Agency (EPA)[7] 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 corn line MZIR260 is considered to be as safe for human consumption as food derived from conventional non-GM corn cultivars.

2.3 Risk management

Following assessment, FSANZ decided to prepare 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 of 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).

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

2.3.1 Regulatory approval

Corn line MZIR260 is a GM food for Code purposes as it is derived from 'an organism which has been modified by gene technology'.[8] The approved draft variation will list corn line MZIR260 in the table to subsection S26—3(4). This amendment will effectively provide permission for the sale and use of food derived from corn line MZIR260 as a GM food in accordance with the Code.

[6] 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.*
[7] The EPA implements and enforces the *Hazardous Substances and New Organisms* (HSNO) *Act 1996*.
[8] ***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'.

Subject to and in accordance with the draft variation, food derived from corn line MZIR260 may enter the Australian and New Zealand food supply as imported food products. These may include starch, grits, meal, flour, oil and sweetener products.

Cultivation of corn line MZIR260 in Australia or New Zealand would require separate prior assessment and approval by GTR in Australia or the EPA in New Zealand.

2.3.2 Labelling

2.3.2.1 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 corn line MZIR260 will 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), S26—3(2A) or S26—3(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 corn line MZIR260 does not have altered characteristics (see section 5.3 of SD1).

Refined products from corn line MZIR260, such as corn starch, oil, and sweeteners, are unlikely to contain any novel DNA or novel protein and will be unlikely to require labelling as 'genetically modified'.

Less refined products derived from corn line MZIR260, such as flour (used in bread), meal (used in polenta) and grits (used in cereals), that contain novel DNA or novel protein 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)).

2.3.3 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 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 for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR[10]-based detection method. This sequence information was supplied by the applicant for A1302.

[9] Now known as the Implementation Subcommittee for Food Regulation.
[10] Polymerase Chain Reaction.

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 development matters is open, accountable, consultative and transparent. Public submissions were invited on a draft variation released for public comment between 22 October 2024 and 4 December 2024. 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 A1302, including the submission received are available on the FSANZ website.[11]

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

2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ 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).[12] 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 (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 application is approved. Under the new approach, FSANZ's assessment was a RIS is not required for this application.

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 was 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 considered permitting the sale and use of food derived from corn line MZIR260.

[11] https://www.foodstandards.gov.au/food-standards-code/applications/application-a1302-food-derived-insect-protected-corn-line-mzir260
[12] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

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 corn line MZIR260.

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

Costs and benefits of permitting the sale and use of food derived from corn line MZIR260

The sale and use of foods derived from corn line MZIR260 will 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 corn line MZIR260, labelling will be required to assist consumers wishing to avoid these products.

Due to the voluntary nature of the permission, manufacturers and retailers will only engage with foods derived from corn line MZIR260 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 that the direct and indirect benefits that would arise from permitting the sale and use of food derived from corn line MZIR260 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 only Standards.

2.5.1.4 Any other relevant matters

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

The applicant has submitted applications for regulatory approval of corn line MZIR260 to other countries, as listed in Table 1.

Table 1. List of countries to whom applications for regulatory approval of MZIR260 have been submitted

Country	Authority	Type of approval sought	Status
United States	United States Department of Agriculture (USDA)	Food	Submitted
	Environmental Protection Agency (EPA)	Environmental release	Submitted
	Food and Drug Administration (FDA)	Food and feed	Submitted
Canada	Canadian Food Inspection Agency (CFIA)	Feed and environmental release	Submitted
	Health Canada (HC)	Food	Submitted
Argentina	National Service of Agrifood Health and Quality of the Secretariat of Agriculture, Livestock and Fisheries (SENASA)	Food and feed	Submitted
	National Advisory Commission on Agricultural Biotechnology of the Secretariat of Agriculture, Livestock and Fisheries (CONABIA)	Environmental release	Submitted
Uruguay	Gabinete Nacional de Bioseguridad y Comisión para la Gestión del Riesgo Commission (CGR-GNBio)	Food, feed and environmental release	Submitted
Japan	Ministry of Agriculture, Forestry and Fisheries-Ministry of Environment (MAFF-MoE)	Environmental release	Submitted
	Ministry of Health, Labour and Welfare (MHMW)	Food	Submitted
Brazil	Comissão Técnica Nacional de Biossegurança (CTNBio)	Food, feed, and environmental release	Approved
Singapore	Singapore Food Agency (SFA)	Food and feed	Submitted
Thailand	Food and Drug Administration Ministry of Public Health (THFDA)	Food	Submitted
China	Ministry of Agriculture and Rural Affairs of the People's Republic of China	Environmental release	Submitted
Columbia	Instituto Columbiano Agropecuario (ICA)	Feed and environmental release	Submitted
	El Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)	Food	Submitted
Korea	Ministry of Food and Drug Safety (MFDS)	Food	Submitted
	Rural Development Administration of South Korea (RDA)	Feed	Submitted
Malaysia	Ministry of Natural Resources and Environmental Sustainability	Food and feed	Submitted
South Africa	Department of Agriculture, Forestry and Fisheries	Food and feed	Submitted
Taiwan	Taiwan Food and Drug Administration (TFDA)	Food	Submitted

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 corn line MZIR260. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from corn line MZIR260 is as safe for human consumption as food derived from other conventional non-GM corn cultivars.

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 corn line MZIR260 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

The provision of DNA sequence information by the applicant (as described in section 2.3.3) satisfies 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 corn line MZIR260 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 by FSANZ in the safety assessment.

- **the promotion of consistency between domestic and international food standards**

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. Corn line MZIR260 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

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

Food Standards (Application A1302 – Food derived from insect-protected corn line MZIR260) 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 A1302 – Food derived from insect-protected corn line MZIR260) 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 2, column headed "*Food derived from*:")

Insert:

(zl) insect-protected corn line MZIR260

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1302 – Food derived from insect-protected corn line MZIR260) 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 A1302 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) – corn line MZIR260. Corn line MZIR260 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 approved a draft variation - the *Food Standards (Application A1302 – Food derived from insect-protected corn line MZIR260) 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 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 corn line MZIR260, in accordance with the Code. Corn line MZIR260 has been genetically modified for protection against lepidopteran insect pests.

4. Documents incorporated by reference

This 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 A1302 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 22 October 2024 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.foodtandards.gov.au.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA).[13] 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

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

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1302 – Food derived from insect-protected corn line MZIR260) Variation*.

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

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

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

alphabetical order, a new paragraph ‘(zl)’ into the column headed ‘*Food derived from:*’ for item 2 of the table to subsection S26—3(4) of the Code. Item 2 of this table is headed ‘Corn’.

The new paragraph (zl) refers to ‘insect-protected corn line MZIR260’.

The effect of the variation is to permit the sale and use of food derived from corn line MZIR260 in accordance with the Code.