

3 April 2023
236-23

Call for submissions – Application A1262

Food derived from insect-protected corn line MON95275

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Bayer CropScience Proprietary Limited 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 MON95275. This corn line has been genetically modified for protection from coleopteran 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.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

All submissions on applications and proposals will be published on our website. 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 as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

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

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made by emailing your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 18 May 2023

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

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

Food Standards Australia New Zealand

Food Standards Australia New Zealand

PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

PO Box 10559
WELLINGTON 6140
NEW ZEALAND
Tel +64 4 978 5630

Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION.....	3
1.3 THE CURRENT STANDARD	3
1.4 REASONS FOR ACCEPTING APPLICATION	4
1.5 PROCEDURE FOR ASSESSMENT	4
2 SUMMARY OF THE ASSESSMENT	4
2.1 RISK ASSESSMENT	4
2.2 RISK MANAGEMENT	5
2.3 RISK COMMUNICATION.....	6
2.3.1 <i>Consultation</i>	6
2.3.2 <i>World Trade Organization (WTO)</i>	7
2.4 FSANZ ACT ASSESSMENT REQUIREMENTS	7
2.4.1 <i>Section 29/59</i>	7
2.4.2 <i>Subsection 18(1)</i>	9
2.4.3 <i>Subsection 18(2) considerations</i>	10
3 DRAFT VARIATION	10
3.1 TRANSITIONAL ARRANGEMENTS.....	ERROR! BOOKMARK NOT DEFINED.
3.1.1 <i>Implementation and review</i>	Error! Bookmark not defined.
3.1.2 <i>Evaluation</i>	Error! Bookmark not defined.
4 REFERENCES	10
ATTACHMENT A – DRAFT VARIATION/S TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE	12
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT.....	14

Supporting document

The [following documents](#)¹ which informed the assessment of this Application are available on the FSANZ website:

SD1 Safety Assessment Report

¹ <https://www.foodstandards.gov.au/code/applications/Pages/Application%20-%20A1262%20-%20Food-derived-from-insect-protected-corn-line-MON95275.aspx>

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Bayer CropScience Proprietary Limited to vary 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 MON95275. Corn line MON95275 has been genetically modified for protection from coleopteran insect pests.

A safety assessment is a critical part of the assessment approval process for all GM food applications. The completed safety assessment for corn line MON95275 is in Supporting Document 1 (SD1). The assessment found no potential public health and safety concerns. Based on the data provided and other information, food derived from corn line MON95275 is considered to be as safe for human consumption as food derived from conventional non-GM corn cultivars.

If approved, food derived from corn line MON95275 may enter the Australian and New Zealand food supply as imported food products. These may include corn starch, grits, meal, flour, oil and sweetener. Viable seeds from corn line MON95275 would not be permitted without prior assessment and approval by the Gene Technology Regulator (GTR) in Australia and the Environmental Protection Authority (EPA) in New Zealand.

Existing labelling requirements for GM food will apply to food derived from corn line MON95275 in accordance with the Code.

For reasons set out above and in the assessment summary, FSANZ has decided to prepare a draft variation to amend Schedule 26 of the Code to include a new item 2 (zf) in the table to subsection S26—3(4) containing a reference to 'insect-protected corn line MON95275' to permit the sale and use of food derived from that corn line. If approved, the effect of the draft variation would be to permit the sale and use of food derived from this corn line in accordance with the Code.

FSANZ seeks submissions on the draft variation.

1 Introduction

1.1 The Applicant

Bayer CropScience Proprietary Limited is a technology provider to a number of sectors including the agriculture sector.

1.2 The Application

Application A1262 was submitted on 16 November 2022. 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 MON95275. This corn line has been genetically modified (GM) for protection from coleopteran insect pests, primarily western corn rootworm (WCR).

Protection from coleopteran insect pests is achieved by the expression of three novel substances: the Mpp75Aa1.1 protein (encoded by the *mpp75Aa1.1* gene) from *Brevibacillus laterosporus*, the Vpb4Da2 protein (encoded by the *vpb4Da2* gene) from *Bacillus thuringiensis* and DvSnf7, a double stranded RNA (dsRNA) that specifically silences the WCR *DvSnf7* gene via RNA interference (RNAi). These novel substances cause midgut damage specifically in WCR larvae.

While FSANZ has assessed and approved numerous applications where *B. thuringiensis* Cry proteins with a similar mechanism of action have been introduced into crops for pest protection, this is the first application to assess the Mpp75Aa1.1 and Vpb4Da2 proteins. The DvSnf7 dsRNA has been previously assessed by FSANZ (Application [A1097](#)).

Food derived from corn line MON95275 may enter the Australian and New Zealand food supply as imported food products. These may include starch, grits, meal, flour, oil and sweetener products. Food from corn line MON95275 containing viable seeds, such as corn cobs, would require prior assessment and approval by the Gene Technology Regulator (GTR)² in Australia and the Environmental Protection Authority (EPA) in New Zealand.

1.3 The current standard

Pre-market approval is necessary before GM foods 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 of the Code sets out the permission and conditions for sale of food that consists of, or has as an ingredient, a GM food. Foods that have been assessed and approved are listed in Schedule 26 of the Code.

Subject to the exceptions listed below, section 1.5.2—4 requires food to be labelled as 'genetically modified' where novel DNA or novel protein is present in the food for sale.

Additionally, foods listed in subsections S26—3(2), (2A) and (3) of Schedule 26 must also be labelled with the words 'genetically modified', as well as any other additional labelling required by the Schedule, regardless of the presence of novel DNA or novel protein in the foods. These foods 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.

² 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*.

The requirement to label as 'genetically modified' applies to a food for sale that consists of, or has as an ingredient (including food additives and processing aids), food that is a *genetically modified food*³. The requirements imposed by section 1.5.2—4 apply only to foods for retail sale and to foods sold to a caterer in accordance with Standard 1.2.1.

The labelling requirement in section 1.5.2—4 does not apply if the GM 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, where novel DNA or novel protein from the substance does not remain 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.

The above labelling requirement also does not apply if the food for sale 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.

If the food for sale is a food not required to bear a label, the labelling information in section 1.5.2—4 must accompany the food or be displayed in connection with the display of the food (in accordance with subsections 1.2.1—9(2) and (3) of Standard 1.2.1).

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

1.4 Reasons for accepting Application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *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 is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Safety assessment

The safety assessment of corn line MON95275 is provided in Supporting Document 1 (SD1) and included the following key elements:

³ 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*).

- 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 MON95275 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 corn line MON95275, or any risks to animals that may consume feed derived from corn line MON95275. Cultivation in 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 corn line MON95275 is considered to be as safe for human consumption as food derived from non-GM corn cultivars.

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 corn line MON95275. If approved, the effect of the draft variation would be to permit the sale and use of food derived from this corn line in accordance with the Code.

2.2.1 Regulatory approval

Corn line MON95275 is a GM food for Code purposes as it is developed from ‘an organism that has been modified using gene technology’. FSANZ is proposing to list corn line MON95275 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 corn line MON95275 as a GM food in accordance with the Code.

2.2.2 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 corn line MON95275 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), 2(A) 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 corn line MON95275 does not have altered characteristics (see section 5.3 of SD1).

Refined products from corn line MON95275 such as corn starch, corn oil and sweeteners are unlikely to contain any novel DNA or novel protein and would be unlikely to require labelling as 'genetically modified'.

Products derived from corn line MON95275 such as flour (used in bread), meal (used in polenta) and grits (used in cereals) 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 GM food or has a GM food as an ingredient to be labelled as 'genetically modified', unless one of the exemptions listed in that subsection apply. If the GM food is present in the food for sale as an ingredient, the 'genetically modified' statement must be in conjunction with the name of the GM food (subsection 1.5.2—4(2)) and it may be included in the statement of ingredients for the food for sale (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-Committee⁴ 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 PCR⁵-based detection method. This sequence information was supplied by the applicant for A1262.

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, FSANZ's social media channels 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 issues raised by the application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account

⁴ Now known as the Implementation Subcommittee for Food Regulation.

⁵ Polymerase Chain Reaction.

all public comments received on this call for submissions.

The applicant and individuals and organisations that make submissions on this application will be notified at each stage of the assessment.

2.3.2 World Trade Organization (WTO)

As members of the WTO, Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to permit food derived from corn line MON95275 is unlikely to have a significant effect on international trade.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

The Office of Impact Analysis (OIA)⁶ granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as varying Schedule 26 is a consequential change of maintaining a permitted schedule of GM foods. Additionally, permitting a new GM food is deregulatory as using the food will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application). This analysis considers permitting the sale and use of food derived from corn line MON95275.

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

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the

⁶ Formerly known as the Office of Best Practice Regulation (OBPR).

effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the sale and use of food derived from corn line MON95275.

Costs and benefits of permitting the sale and use of food derived from corn line MON95275

The sale and use of foods derived from corn line MON95275 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 corn line MON95275, labelling is required to assist consumers wishing to avoid these products to do so.

Due to the voluntary nature of the permission, manufacturers and retailers would only engage with foods derived from corn line MON95275, 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 MON95275, most likely outweigh the associated costs.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than varying Schedule 26 as a result of application A1262.

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 corn line MON95275 to other countries, as listed in Table 1.

Cultivation in Australia or New Zealand would require independent assessment and approval by the Gene Technology Regulator and New Zealand EPA, respectively.

Table 1: List of countries to whom applications for regulatory approval of MON95275 have been submitted

Country	Authority	Type of approval sought	Status
Brazil	National Biosafety Commission (CTNBio)	Food, Feed, Environment	Submitted
United States	Food and Drug Administration (FDA)	Food and Feed	Submitted
	United States Department of Agriculture (USDA)	Environment	Submitted

Country	Authority	Type of approval sought	Status
Brazil	National Biosafety Commission (CTNBio)	Food, Feed, Environment	Submitted
	Environmental Protection Agency (EPA)	Environment	Submitted
Canada	Health Canada (HC)	Food	Submitted
	Canadian Food Inspection Agency (CFIA)	Feed, Environment release	Submitted
Japan	Ministry of Health, Labour and Welfare (MHLW)	Food	Submitted
	Ministry of Agriculture, Forestry and Fisheries	Feed	Submitted
Taiwan	Taiwan Food and Drug Administration (TFDA)	Food	Submitted
	Council of Agriculture (COA)	Feed	Submitted
European Union	European Food Safety Authority (EFSA)	Food and Feed	Submitted
Philippines	Agriculture-Bureau of Plant Industry (BPI)	Food, Feed and Processing	Submitted
Indonesia	Indonesian Food and Drug Authority (BPOM)	Food	Submitted
Thailand	Thailand Food and Drug Administration	Import	Submitted

Further 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 corn line MON95275. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from corn line MON95275 is as safe as food derived from other non-GM corn lines.

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 corn line MON95275 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 (as described in Section 2.2.3) satisfies this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2009). Based on these principles, the risk analysis undertaken for corn line MON95379 used the best scientific evidence available. The applicant submitted a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the applicant, other available resource material including published scientific literature and general technical information was used in the safety assessment.

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

This is not a consideration as there are no relevant international standards.

- **the desirability of an efficient and internationally competitive food industry**

The inclusion of GM foods in the food supply, providing there are no safety concerns, allows for innovation by developers and a widening of the technological base for producing foods. Corn line MON95275 is a new food crop designed to provide growers with an additional control option for coleopteran 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 Forum on Food Regulation**

No specific policy guidelines have been developed.

3 Draft variation

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

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

4 References

Codex (2009) Foods derived from modern biotechnology, Second Edition. Codex Alimentarius Commission, Rome. <http://www.fao.org/3/a1554e/a1554e00.htm>

Attachments

- A. Draft variation to the Australia New Zealand Food Standards Code
- B. Draft Explanatory Statement

Attachment A – Draft variation to the Australia New Zealand Food Standards Code



Food Standards (Application A1262 – Food derived from insect-protected corn line MON95275) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of the variation.

Dated [To be completed by the delegate]

Christel Leemhuis
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 A1262 – Food derived from insect-protected corn line MON95275) 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)

Insert:

(zf) insect-protected corn line MON95275

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1262 – Food derived from insect-protected corn line MON95275) 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 A1262 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) - corn line MON95275. Corn line MON95275 has been genetically modified for protection from coleopteran 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 A1262 – Food derived from insect-protected corn line MON95275) 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).

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 Ministers 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 corn line MON95275, in accordance with the Code. Corn line MON95275 has been genetically modified for protection from coleopteran 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 A1262 will include one round of public consultation following an assessment and the preparation of a draft variation. A call for submissions (including the draft variation) will be open for a six-week period.

The Office of Impact Analysis⁷ granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting new GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new GM foods is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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

Item [1] of the Schedule to the draft variation would insert, in alphabetical order, a new paragraph '(zf)' into item 2 of the table to subsection S26—3(4) of the Code.

The new paragraph (zf) refers to 'insect-protected corn line MON95275'.

If approved, the draft variation would permit the sale and use of food derived from corn line MON95275 in accordance with the Code.

⁷ Formerly known as the Office of Best Practice Regulation (OBPR).