

19 March 2024
285-24

Call for submissions – Application A1287

Food derived from short-stature corn line MON94804

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Bayer CropScience Proprietary Limited 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 MON94804. This corn line has been genetically modified to have reduced overall plant height (short-stature). A draft food regulatory measure has been prepared. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application need to be made using the [FSANZ Consultation Hub](https://consultations.foodstandards.gov.au/) (<https://consultations.foodstandards.gov.au/>). As a trial, FSANZ is consulting on this application using the FSANZ Consultation Hub, built on the Citizen Space platform.

All submissions on this application will be published on the FSANZ Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published 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 [How to make a submission](#).

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

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 30 April 2024

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:

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Supporting document

The following document which informed the assessment of this application is available on the [FSANZ website](#)¹:

SD1 Safety Assessment Report

¹ <https://www.foodstandards.gov.au/food-standards-code/applications/a1287-food-derived-short-stature-corn-line-mon94804>

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Bayer CropScience Proprietary Limited to request a variation to Schedule 26 in the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): corn line MON94804. Corn line MON94804 has been genetically modified (GM) to have reduced overall plant height.

A safety assessment is a critical part of the assessment approval process for all GM food applications. The completed safety assessment for corn line MON94804 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 MON94804 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 MON94804 may enter the Australian and New Zealand food supply as imported food products. These may include corn starch, grits, meal, flour, oil and sweetener. Food consisting of or containing viable seeds from corn line MON94804, such as corn cobs or kernels, would not be permitted without prior assessment and approval by the Gene Technology Regulator in Australia and the Environmental Protection Authority in New Zealand.

If approved, existing labelling requirements for GM food would apply to food derived from corn line MON94804 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 (zk) in the table to subsection S26—3(4) containing a reference to 'short-stature corn line MON94804' to permit the sale and use of food derived from corn line MON94804. 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 A1287 was submitted on 29 September 2023. 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 MON94804. This corn line has been genetically modified (GM) to have an overall reduced plant height.

The short-stature of MON94804 is due to the presence of one novel substance: the GA20ox_SUP microRNA (miRNA). This miRNA suppresses two genes involved in the synthesis of gibberellin (GA), a plant hormone involved in plant growth and development. The resulting decrease in GA levels in the stalk leads to an overall reduction in plant height. The GA20ox_SUP miRNA has not been previously assessed by FSANZ.

If approved, food derived from corn line MON94804 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 consisting of or containing viable seeds from corn line MON94804, such as corn cobs or kernels, would require prior assessment and approval by the Gene Technology Regulator (GTR)² in Australia and the Environmental Protection Authority (EPA)³ 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.

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

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*.

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

*genetically modified food*⁴. The requirements imposed by section 1.5.2—4 apply 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 and is not in a package, 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 the 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.

⁴ 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*).

2 Summary of the assessment

2.1 Safety assessment

The safety assessment of corn line MON94804 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 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 MON94804 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 MON94804, or any risks to animals that may consume feed derived from corn line MON94804. Permission to cultivate corn line MON94804 in or to import viable seeds into Australia or New Zealand would require separate regulatory assessment and approval by the GTR in Australia and by the EPA in New Zealand.

No potential public health and safety concerns have been identified.

Based on the data provided in the present application and other available information, food derived from corn line MON94804 is considered to be as safe for human consumption as food derived from conventional 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 MON94804. 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 MON94804 is a GM food for Code purposes as it is derived from 'an organism which has been modified by gene technology'. FSANZ is proposing to list corn line MON94804 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 MON94804 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 MON94804 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), S26—3(2A) or S26—3(3) of Schedule 26 with a condition that the labelling must comply with section 1.5.2—4 of Standard 1.5.2.

FSANZ has determined that food derived from corn line MON94804 does not have altered characteristics (see section 5.3 of SD1).

Refined products from corn line MON94804 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 MON94804 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. 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)).

2.2.3 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-Committee⁵ to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food produced using gene technology (GM applications).

The EAG indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR⁶-based detection method. This sequence information was supplied by the applicant for A1287.

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.

⁵ Now known as the Implementation Subcommittee for Food Regulation.

⁶ Polymerase Chain Reaction.

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

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received 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 World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to permit food derived from corn line MON94804 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

FSANZ has considered the costs and benefits of permitting the sale and use of food derived from corn line MON94804, as required by the FSANZ Act. A Regulatory Impact Statement (RIS) has not been prepared.

FSANZ expects that the benefits of the permission will likely exceed the costs. This assessment is discussed in more detail below.

Changes to Regulatory Impact Statement requirements

Impact analysis arrangements are no longer required to be finalised with the Office of Impact Analysis (OIA), as a result of changes made to the impact analysis requirements⁷. These changes mean FSANZ is responsible for deciding whether a RIS should be developed for proposals to amend the Code.

Prior to these changes, the OIA advised FSANZ that a RIS was not required for applications relating to GM food. This is because applications relating to permitting the use of GM food 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.

On this basis, FSANZ's assessment is that a RIS is not required for this application.

⁷ [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](#)

Consideration of costs and benefits under the FSANZ Act

FSANZ 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 status quo is rejecting the application.

This analysis considers permitting the proposed sale and use of food derived from a new food produced using gene technology (GM food): corn line MON94804.

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 approving the variation to the Code proposed by the application.

The benefits and costs of permitting corn line MON94804

Use of the permission for the sale and use of foods derived from corn line MON94804 would be voluntary.

Short-stature corn line MON 94804 is substantially equivalent to other conventional corn lines except it has a shorter height.

Growers may benefit from the permission because shorter corn crops:

- experience reduced lodging⁸ and green snap in high winds and challenging weather, reducing the risk of crop losses
- can be accessed year-round by standard farming equipment, which allows:
 - pesticides to be applied more effectively and efficiently, potentially reducing pesticide costs
 - key nutrients to be applied as needed, potentially increasing yield.

The magnitude of these benefits has not been assessed.

Any benefits experienced by growers may flow through to other elements of the food supply chain that use corn grown using the permission, for example exporters, fresh food retailers or manufacturers of processed food.

From a regulatory impact perspective, FSANZ does not anticipate the permission results in cost impacts for industry. This is because use of the permission is voluntary, businesses will only engage with foods derived from corn line MON94804 where they believe a net benefit exists for them. These businesses may experience costs related to the permission, but only where they have chosen to use the permission⁹.

⁸ Lodging is the displacement of stems from their vertical position, resulting in reductions in crop yield and quality.

⁹ For example, a processed food manufacturer may include corn derived from corn line MON94804 in an existing product, replacing corn from another source. This manufacturer will be required to re-label this product to state it contains genetically modified ingredients. While updating the label is required by the Food Standards Code, it is not a regulatory cost because the manufacturer did not have to use corn derived from corn line MON94804.

Any cost savings experienced by any part of the food industry may be passed onto consumers.

There are not expected to be any significant costs to consumers, because:

- they will have an informed choice as all products containing GM food are required to be labelled
- FSANZ has assessed foods derived from corn line MON94804 as safe to consume.

There are not expected to be any significant costs or impacts for governments. 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 assessment

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 MON94804 most likely outweigh the associated costs.

FSANZ will consider all information received from the call for submissions, and update the assessment of the costs and benefits if required. This may result in FSANZ arriving at a different conclusion.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

The applicant has submitted applications for regulatory approval of corn line MON94804 to other countries, as listed in Table 1.

Cultivation in Australia or New Zealand or the importation of viable seed would require independent assessment and approval by the GTR in Australia and EPA in New Zealand, respectively.

Table 1: List of countries to whom applications for regulatory approval of MON94804 have been submitted

Country	Authority	Type of approval sought	Status
Argentina	National Service of Agri-Food Health and Quality (SENASA)	Food and Feed	Approved
	National Advisory Commission on Agricultural Biotechnology (CONABIA)	Environment	Submitted
Brazil	National Biosafety Committee (CTNBio)	Food, Feed, Environment	Approved
Canada	Canadian Food Inspection Agency (CFIA)	Feed and Environment	Approved
	Health Canada (HC)	Food	Approved
China	Ministry of Agriculture and Rural Affairs (MARA)	Food and Feed	Submitted
European Union	European Food Safety Authority (EFSA)	Food and Feed	Submitted
Japan	Ministry of Agriculture, Forestry and Fisheries (MAFF)/MOE	Environment	Submitted
	Ministry of Agriculture, Forestry and Fisheries (MAFF)/MME	Feed	Submitted
	Ministry of Health, Labour and Welfare (MHLW)	Food	Submitted
Korea	Ministry of Food and Drug Safety (MFDS)	Food	Submitted
	Rural Development Association (RDA)	Feed	Submitted
Malaysia	Ministry of Natural Resources, Environment and Climate Change (NRECC)	Food and Feed	Submitted
Taiwan	Taiwan Food and Drug Administration (TFDA)	Food	Submitted
	Ministry of Agriculture (MoA)	Feed	Submitted
Thailand	Thailand Food and Drug Administration (FDA)	Food	Submitted
United States	Food and Drug Administration (FDA)	Food and Feed	Submitted
	Environmental Protection Agency (EPA)	Environment	Submitted
	United States Department of Agriculture (USDA)	Determination of nonregulated status	Approved

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ's assessment did not identify any public health and safety concerns with food derived from corn line MON94804. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from corn line MON94804 is as safe for human consumption as food derived from other conventional 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 MON94804 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 by FSANZ for corn line MON94804 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**

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 MON94804 is a new food crop designed to have a reduced plant height compared to conventional corn, providing growers with potential agronomic and environmental benefits.

- **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) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome. <http://www.fao.org/3/a1554e/a1554e00.htm>

Attachments

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

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



Food Standards (Application A1287 – Food derived from short-stature corn line MON94804) 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 A1287 – Food derived from short-stature corn line MON94804) 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:

(zk) short-stature corn line MON94804

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1287 – Food derived from short-stature corn line MON94804) 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 A1287 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 MON94804. Corn line MON94804 has been genetically modified to have overall reduced plant height (short-stature). The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1287 – Food derived from short-stature corn line MON94804) 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 MON94804, in accordance with the Code. Corn line MON94804 has been genetically modified to have overall reduced plant height.

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 A1287 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-week period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)¹⁰. Impact analysis is no longer required to be finalised with the OIA. Prior to those changes, the OIA had 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 draft variation related to the application is approved. The standing exemption relates to the introduction of a food to the food supply that has been determined to be safe. Under the new approach, the Authority's assessment is that a regulatory impact statement is not required for this application.

6. Statement of compatibility with human rights

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

7. Variation

Clause 1 of the draft variation provides that the name of the variation is the *Food Standards (Application A1287 – Food derived from herbicide-tolerant and insect-protected corn line MON94804) Variation*.

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

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

Item [1] of the Schedule to the draft variation would amend Schedule 26 by inserting, in alphabetical order, new paragraph '(zk)' 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'.

¹⁰ [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](#)

The new paragraph (zk) refers to 'short-stature corn line MON94804'.

If approved, the draft variation would permit the sale and use of food derived from corn line MON94804 in accordance with the Code.