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Approval report – Application A1270

Food derived from herbicide-tolerant and insect-protected corn line DP51291

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Corteva Agriscience Australia 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 DP51291. This corn line has been genetically modified for tolerance to the herbicide glufosinate and protection from coleopteran insect pests.

On 3 August 2023, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 6 December 2023. The Food Ministers' Meeting¹ was notified of FSANZ's decision on 15 December 2023.

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 [FSANZ website](#)²:

SD1 Supporting Document 1 - Safety Assessment Report

² <https://www.foodstandards.govt.nz/food-standards-code/applications/A1270-Food-derived-from-herbicide-tolerant-and-insect-protected-corn-line-DP51291>

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Corteva Agriscience Australia Proprietary Limited seeking to amend 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 DP51291. This corn line has been genetically modified for tolerance to the herbicide glufosinate and protection from coleopteran insect pests.

This application was the second to be assessed under a project between FSANZ and the Food Directorate of Health Canada for the joint preparation and sharing of safety assessments for GM foods, referred to as safety assessment sharing.

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

The safety assessment of corn line DP51291 is in Supporting Document 1 (SD1). No potential public health and safety concerns have been identified. Based on the data provided and other information, food derived from corn line DP51291 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 DP51291 in accordance with the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 3 August 2023. Two submissions were received in the six-week consultation period. FSANZ has had regard to both submissions and addressed an issue raised in one of those submissions (see section 2.1).

For reasons summarised in this report and following its assessment, 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 (zg) for item 2 in the table to subsection S26—3(4) containing a reference to 'herbicide-tolerant and insect-protected corn line DP51291'. The effect of the approved draft variation will be to permit the use and sale of food derived from this corn line in accordance with the Code.

1 Introduction

1.1 The applicant

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

1.2 The application

Application A1270 was submitted on 7 February 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 DP51291. This corn line has been genetically modified (GM) for tolerance to the herbicide glufosinate and protection from the coleopteran insect pest western corn rootworm (WCR). DP51291 expresses 3 novel substances, summarised in Table 1.

Table 1: Novel substances expressed in DP51291

Protein	Gene	Donor organism	Function	Previously assessed by FSANZ?
IPD072Aa	<i>ipd072Aa</i>	<i>Pseudomonas chlororaphis</i>	Confers protection against corn rootworm	Yes. Application A1202
Phosphinothricin acetyltransferase (PAT)	<i>mo-pat</i>	<i>Streptomyces viridochromogenes</i>	Glufosinate tolerance	Yes. Numerous applications
Phosphomannose isomerase (PMI)	<i>pmi</i>	<i>Escherichia coli</i> K-12	Selectable marker	Yes. Applications A564, A580, A1001, A1060 and A1202

1.2.1 Safety assessment sharing with Health Canada

The application was the second to be assessed under a project being conducted by FSANZ and the Food Directorate of Health Canada for the joint preparation and sharing of safety assessments for food produced using gene technology (GM food)³, referred to as safety assessment sharing.

The assessment sharing project is the result of a collaboration between FSANZ and Health Canada that commenced in 2013 and builds on a long history of information sharing and cooperation at an international level on GM foods. The purpose of the collaboration was to explore opportunities for improving the efficiency of GM food safety assessment by streamlining the assessment process. The goal of safety assessment sharing is to establish a system where a safety assessment is jointly prepared that meets the separate requirements of both agencies when undertaking their own separate and independent assessments.

Extensive work undertaken in the early stages of the collaboration confirmed the compatibility of FSANZ's and Health Canada's safety assessment approaches, both in terms

³ <https://www.foodstandards.gov.au/science/international/Pages/GM--food-safety-assessment-sharing.aspx>

of how safety assessments are conducted and the conclusions that are reached. Both agencies also adhere to internationally agreed principles and guidelines for the conduct of GM food safety assessment 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.

Under the system, where GM food approval is being sought in Canada, Australia and New Zealand, an applicant may request their application be assessed using a safety assessment sharing approach. Applications must still be submitted to both agencies and assessed separately by each agency according to their respective requirements, but only one documented food safety assessment is jointly prepared by both agencies.

The first application assessed under the assessment sharing program was [application A1216](#)⁴ (canola line MON94100). For A1216, the joint food safety assessment was initially prepared by Health Canada, and then provided to FSANZ for FSANZ's review and confirmation that it met all relevant requirements for Australian and New Zealand purposes. Following confirmation that these requirements were met, the jointly prepared safety assessment was used as part of the FSANZ assessment.

For corn line DP51291 (the current application), the joint food safety assessment was initially prepared by FSANZ and then provided to Health Canada for review and use as part of Health Canada's separate and independent approval processes.

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 *genetically modified food*⁵. 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:

⁴ <https://www.foodstandards.gov.au/food-standards-code/applications/A1216>

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*).

- 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 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

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 3 August 2023. The consultation period was six weeks.

Submissions were received from:

- New Zealand Food Safety (NZFS)

- Grain Producers Australia (GPA)

Both submissions supported the proposed draft variation to Schedule 26. The response to an issue raised in one of the submissions is provided in Table 2.

Table 2: Summary of issues / comments

Issue	Raised by	FSANZ response
The requirement for labelling as “genetically modified” if there is any novel protein or DNA in the final food is confusing and misleading for consumers, and may imply a safety concern where in fact none exists.	GPA	<p>The requirement for labelling as “genetically modified” is not based on safety concerns. All GM foods must be assessed as safe before they are approved for sale. The purpose of the labelling requirement is to assist consumers to make an informed choice. This requirement was adopted by food ministers in 2000.</p> <p>Promoting the benefits of a particular food or technology is not a function of FSANZ under the FSANZ Act.</p> <p>The Code does not regulate ‘non-GM’ claims. These types of representations are made voluntarily by food manufacturers and are subject to relevant consumer protection legislation in Australia and New Zealand which prohibit representations about food that are, or are likely to be, false, misleading or deceptive.</p>

2.2 Safety assessment

The safety assessment of corn line DP51291 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 DP51291 was restricted to human food safety and nutritional issues. This assessment therefore did not address any risks to the environment that may occur as the result of growing corn line DP51291, or any risks to animals that may consume feed derived from corn line DP51291. Cultivation in Australia or New Zealand would require separate regulatory assessment and approval by the Gene Technology Regulator (GTR)⁶ in Australia and the Environmental Protection Authority (EPA)⁷ in New Zealand.

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*

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 DP51291 is considered to be as safe for human consumption as food derived from non-GM corn cultivars.

2.3 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.

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

2.3.1 Regulatory approval

Corn line DP51291 is a GM food for Code purposes as it is developed from ‘an organism which has been modified by gene technology’. The approved draft variation lists corn line DP51291 in the table to subsection S26—3(4). Following gazettal, this will provide permission for the sale and use of food derived from corn line DP51291 as a GM food in accordance with the Code.

Food derived from corn line DP51291 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 DP51291 containing viable seeds, such as corn cobs, would require separate prior assessment and approval by the GTR in Australia and the EPA in New Zealand.

2.3.2 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food for sale derived from a GM food such as corn line DP51291 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), 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 DP51291 does not have altered characteristics (see section 5.3 of SD1).

Refined products from corn line DP51291 such as corn starch, corn oil and sweeteners are unlikely to contain any novel DNA or novel protein and will be unlikely to require labelling as ‘genetically modified’.

Products derived from corn line DP51291 such as flour (used in bread), meal (used in polenta) and grits (used in cereals) will likely contain novel DNA or novel protein, and if so, will require labelling as ‘genetically modified’.

Section 1.5.2—4 of the Code generally requires a food for sale that consists of a 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)).

2.3.3 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-Committee⁸ 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 PCR⁹-based detection method. This sequence information was supplied by the applicant for A1270.

2.4 Risk communication

2.4.1 Consultation

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

The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions were invited on a draft variation which was released for public comment between 3 August 2023 and 14 September 2023. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standards News. Subscribers and interested parties were also notified.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission was considered as part of the decision making process by FSANZ. All comments are valued and contribute to the rigour of our assessment.

Documents relating to Application A1270, including submissions received, are available on the [FSANZ website](#)¹⁰.

The draft variation was considered for approval by the FSANZ Board having regard to the 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 has had regard to the following matters in section 29 of the FSANZ Act:

⁸ Now known as the Implementation Subcommittee for Food Regulation.

⁹ Polymerase Chain Reaction.

¹⁰ <https://www.foodstandards.gov.au/food-standards-code/applications/A1270-Food-derived-from-herbicide-tolerant-and-insect-protected-corn-line-DP51291>

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)¹¹. 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 was not required for applications relating to GM foods. This is because applications relating to permitting the use of GM foods that have been determined to be safe are considered to be minor and deregulatory in nature, as the use of the GM food will be voluntary if the draft variation related to the application is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

FSANZ, however, gave 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 DP51291.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought 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 DP51291.

Costs and benefits of permitting the sale and use of food derived from corn line DP51291

The sale and use of foods derived from corn line DP51291 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 DP51291, labelling will be 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 DP51291, 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 at the call for submissions stage was that the direct and indirect benefits that would arise from permitting the sale and use of food derived from corn line DP51291, would most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

¹¹ [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](https://www.pmc.gov.au/regulatory-impact-analysis-guide-for-ministers-meetings-and-national-standard-setting-bodies)

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 and EPA, respectively.

The applicant has submitted applications for regulatory approval of corn line DP51291 to other countries, as listed in Table 2.

Table 2: List of countries to whom applications for regulatory approval of DP51291 have been submitted

Country	Authority	Type of approval sought	Status
Colombia	National Institute for Food and Drug Surveillance (INVIMA)	Food	Submitted
Canada	Health Canada (HC)	Food	Submitted
	Canadian Food Inspection Agency (CFIA)	Feed, Environmental release	Submitted
European Union	European Food Safety Authority (EFSA)	Food and Feed	Submitted
Taiwan	Taiwan Food and Drug Administration (TFDA)	Food	Submitted

Further 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 DP51291. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from corn line DP51291 is as safe for human consumption as food derived from conventional non-GM corn lines.

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 DP51291 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 for corn line DP51291 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 materials including published scientific literature and general technical information were 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 DP51291 is a new food crop designed for tolerance to the herbicide glufosinate and 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 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) Foods derived from modern biotechnology, Second Edition. 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 A1270 – Food derived from herbicide-tolerant and insect-protected corn line DP51291) 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 A1270 – Food derived from herbicide-tolerant and insect-protected corn line DP51291) 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:*”, after paragraph (zf))

Insert:

(zg) herbicide-tolerant and insect-protected corn line DP51291

Attachment B Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1270 – Food derived from herbicide-tolerant and insect-protected corn line DP51291) 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 A1270 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 DP51291. Corn line DP51291 has been genetically modified for tolerance to the herbicide glufosinate and protection from coleopteran 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 A1270 – Food derived from herbicide-tolerant and insect-protected corn line DP51291) Variation*.

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

2. Variation is a legislative instrument

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

This instrument is not subject to the disallowance or 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 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 DP51291, in accordance with the Code. Corn line DP51291 has been genetically modified for tolerance to the herbicide glufosinate and protection from coleopteran insect pests.

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1270 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 3 August 2023 for a six-week consultation period.

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 was not required for applications relating to GM foods. This is because applications relating to permitting the use of GM foods that have been determined to be safe are considered to be minor and deregulatory in nature, as the use of the GM food will be voluntary if the draft variation related to the application is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1270 – Food derived from herbicide-tolerant and insect-protected corn line DP51291) 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

¹² [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](https://www.pmc.gov.au/regulatory-impact-analysis-guide-for-ministers-meetings-and-national-standard-setting-bodies)

alphabetical order, a new paragraph '(zg)' 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 (zg) refers to 'herbicide-tolerant and insect-protected corn line DP51291'.

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