

**16 February 2024**  
**281-24**

## Approval report – Application A1272

### Food derived from herbicide-tolerant and insect-protected corn line DP915635

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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 DP915635. This corn line has been genetically modified for tolerance to the herbicide glufosinate and protection from coleopteran insect pests.

On 7 September 2023, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received one submission.

FSANZ approved the draft variation 2 February 2024. The Food Ministers' Meeting<sup>1</sup> was notified of FSANZ's decision on 16 February 2024.

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

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<sup>1</sup> 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](#)<sup>2</sup>:

SD1      Supporting Document 1 – Safety assessment report

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<sup>2</sup> <https://www.foodstandards.gov.au/food-standards-code/applications/A1272-Food-derived-from-herbicide-tolerant-and-insect-protected-corn-line-DP915635>

## 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 DP915635. This corn line has been genetically modified for tolerance to the herbicide glufosinate and protection from coleopteran insect pests, particularly corn rootworm.

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 DP915635 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 DP915635 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 DP915635 in accordance with the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 7 September 2023. One submission was received in the six-week consultation period. FSANZ has had regard to this submission.

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 (zh) for item 2 in the table to subsection S26—3(4) containing a reference to 'herbicide-tolerant and insect-protected corn line DP915635'. The effect of the approved draft variation will be to permit the sale and use of food derived from this corn line in accordance with the Code.

# 1 Introduction

## 1.1 The applicant

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

## 1.2 The application

Application A1272 was submitted on 3 April 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 DP915635. This corn line has been genetically modified (GM) for tolerance to the herbicide glufosinate and protection from coleopteran insect pests, particularly corn rootworm. DP915635 expresses 3 novel substances, summarised in Table 1.

**Table 1: Novel substances expressed in DP915635**

Protein	Gene	Donor organism	Function	Previously assessed by FSANZ?
IPD079Ea	<i>ipd079Ea</i>	<i>Ophioglossum pendulum</i>	Confers protection against corn rootworm	No
Phosphinothricin acetyltransferase (PAT)	<i>mo-pat</i>	<i>Streptomyces viridochromogenes</i>	Glufosinate tolerance	Yes (29 previous applications)
Phosphomannose isomerase (PMI)	<i>pmi</i>	<i>Escherichia coli</i> K-12	Selectable marker	Yes. (7 previous applications)

## 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*<sup>3</sup>. 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 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.

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<sup>3</sup> 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 findings

### 2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 7 September 2023. The consultation period was six weeks.

One submission was received by FSANZ - a submission from New Zealand Food Safety (NZFS). This submission supported the proposed draft variation to Schedule 26. No issues were raised.

### 2.2 Safety assessment

The safety assessment of corn line DP915635 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 DP915635 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 DP915635, or any risks to animals that may consume feed derived from corn line DP915635. Cultivation in Australia or New Zealand would require separate regulatory assessment and approval by the Gene Technology Regulator (GTR)<sup>4</sup> in Australia and the Environmental Protection Authority (EPA)<sup>5</sup> in New Zealand.

### 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 the submission 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 DP915635 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

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<sup>4</sup> 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*.

<sup>5</sup> The EPA implements and enforces the *Hazardous Substances and New Organisms (HSNO) Act 1996*.

DP915635 in the table to subsection S26—3(4). This amendment will effectively provide permission for the sale and use of food derived from corn line DP915635 as a GM food in accordance with the Code.

Food derived from corn line DP915635 may enter the Australian and New Zealand food supply as imported food products. These may include starch, grits, meal, flour, oil and sweetener products. Cultivation of corn line DP915635 or importation of GM seeds 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 DP915635 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), (2A) or (3) of Schedule 26 as being subject to the condition that the labelling must comply with section 1.5.2—4 of Standard 1.5.2 (such food has altered characteristics).

FSANZ has determined that food derived from corn line DP915635 does not have altered characteristics (see section 5.3 of SD1).

Refined products from corn line DP915635 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 DP915635 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. 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, this statement 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-Committee<sup>6</sup> to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food produced using gene technology (GM applications).

The EAG indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR<sup>7</sup>-based detection method. This sequence information was supplied by the applicant for A1272.

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<sup>6</sup> Now known as the Implementation Subcommittee for Food Regulation.

<sup>7</sup> Polymerase Chain Reaction.

## 2.4 Risk communication

### 2.4.1 Consultation

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

The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions were invited on a draft variation which was released for public comment between 7 September 2023 and 20 October 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 applications to amend the Code. All submissions are 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 A1272, including the received submission, are available on the [FSANZ website](#)<sup>8</sup>.

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:

### 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)<sup>9</sup>. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for applications relating to GM foods. 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 RIS 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)).

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<sup>8</sup> <https://www.foodstandards.gov.au/food-standards-code/applications/A1272-Food-derived-from-herbicide-tolerant-and-insect-protected-corn-line-DP915635>

<sup>9</sup> [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](#)



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 DP915635.

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 DP915635.

#### *Costs and benefits of permitting the sale and use of food derived from corn line DP915635*

The sale and use of foods derived from corn line DP915635 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 DP915635, 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 DP915635 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 DP915635 would most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

#### **2.5.1.2 Other measures**

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

#### **2.5.1.3 Any relevant New Zealand standards**

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

#### **2.5.1.4 Any other relevant matters**

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

The applicant has submitted applications for regulatory approval of corn line DP915635 to other countries, as listed in Table 2.

**Table 2: List of countries to whom applications for regulatory approval of DP915635 have been submitted**

Country	Authority	Type of approval sought	Status
Canada	Canadian Food Inspection Agency (CFIA) – Plant Biosafety Office (PBO)	Cultivation	Approved
	Health Canada	Food	Approved
	Canadian Food Inspection Agency (CFIA) – Animal Feed Division (AFD)	Feed	Approved
Columbia	Instituto Colombiano Agropecuario (ICA)	Feed	Approved
	El Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)	Food	Approved
European Union	European Food Safety Authority (EFSA)	Food and Feed	Submitted
Japan	Ministry of Health, Labour and Welfare (MHLW)	Food	Submitted
	Ministry of Agriculture, Forestry and Fisheries (MAFF)	Feed	Submitted
Taiwan	Ministry of Health and Welfare (MOHW); Taiwan Food and Drug Administration (TFDA)	Food	Approved
United States	Food and Drug Administration (FDA)	Food and Feed	Approved
	United States Department of Agriculture (USDA)	Determination of nonregulated status	Submitted

Other relevant matters are considered below.

## **2.5.2. Subsection 18(1)**

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

### **2.5.2.1 Protection of public health and safety**

FSANZ's assessment did not identify any public health and safety concerns with food derived from corn line DP915635. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from corn line DP915635 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 DP915635 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 DP915635 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 DP915635 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 A1272 – Food derived from herbicide-tolerant and insect-protected corn line DP915635) Variation

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

Dated [To be completed by the delegate]

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 A1272 – Food derived from herbicide-tolerant and insect-protected corn line DP915635) 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 (zg))**

Insert:

(zh) herbicide-tolerant and insect-protected corn line DP915635

## Attachment B – Explanatory Statement

### EXPLANATORY STATEMENT

*Food Standards Australia New Zealand Act 1991*

#### ***Food Standards (Application A1272 – Food derived from herbicide-tolerant and insect-protected corn line DP915635) 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 A1272 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 DP915635. Corn line DP915635 has been genetically modified for tolerance to the herbicide glufosinate and protection from coleopteran insect pests, particularly corn rootworm. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards (Application A1272 – Food derived from herbicide-tolerant and insect-protected corn line DP915635) 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](http://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 DP915635, in accordance with the Code. Corn line DP915635 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 A1272 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 7 September 2023 for a six-week consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)<sup>10</sup>. 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 A1272 – Food derived from herbicide-tolerant and insect-protected corn line DP915635) 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 alphabetical order, a new paragraph '(zh)' into the column headed '*Food derived from:*' for

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<sup>10</sup> [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)



item 2 of the table to subsection S26—3(4) of the Code. Item 2 of this table is headed 'Corn'.

The new paragraph (zh) refers to 'herbicide-tolerant and insect-protected corn line DP915635'.

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