19 June 2024
294-24

Approval report – Application A1281

Food derived from herbicide-tolerant and insect-protected corn line DP910521

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 DP910521. This corn line has been genetically modified for tolerance to the herbicide glufosinate and protection from lepidopteran insect pests.

On 23 January 2024, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 4 June 2024. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 19 June 2024.

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.gov.au/food-standards-code/applications/a1281-food-derived-herbicide-tolerant-and-insect-protected-corn

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from Corteva Agriscience Australia Proprietary Limited seeking a variation to Schedule 26 in the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): corn line DP910521. Corn line DP910521 has been genetically modified for tolerance to the herbicide glufosinate and protection from lepidopteran insect pests, including fall armyworm.

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

The safety assessment of corn line DP910521 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 DP910521 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 DP910521 in accordance with the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 23 January 2024. Four submissions were received in the six-week consultation period. FSANZ has had regard to these submissions.

For reasons set out in this report, FSANZ has decided to approve the draft variation proposed at the call for submissions without change. The approved draft variation will amend Schedule 26 of the Code to include a new paragraph (zj) for item 2 in the table to subsection S26—3(4) containing a reference to ‘herbicide-tolerant and insect-protected corn line DP910521’. 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 A1281 was submitted on 27 July 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 DP910521. This corn line has been genetically modified (GM) for tolerance to the herbicide glufosinate and protection from lepidopteran insect pests, including fall armyworm. DP910521 expresses 3 novel substances, summarised in Table 1.

Table 1: Novel substances expressed in DP910521

Protein	Gene	Donor organism	Function	Previously assessed by FSANZ?
Cry1B.34	*cry1B.34*	*Bacillus thuringiensis*	Confers protection against lepidopteran insect pests	No
Phosphinothricin acetyltransferase (PAT)	*mo-pat*	*Streptomyces viridochromogenes*	Glufosinate tolerance	Yes (34 previous applications)
Phosphomannose isomerase (PMI)	*pmi*	*Escherichia coli* K-12	Selectable marker	Yes (8 previous applications)

1.3 The current standard

Pre-market approval

Standard 1.1.1 of the Code provides that, unless expressly permitted by the Code, a food for sale cannot be, or have as an ingredient or component, a GM food.[3] Standard 1.1.2 defines what is a 'food produced using gene technology' (referred to generally as a GM food in this report) for this purpose.[4]

The above in effect requires pre-market approval of a GM food before it can enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment.

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

Standard 1.5.2 sets out the permission and conditions for sale of a food that is, or has as an ingredient, a GM food. Permitted GM foods are listed in Schedule 26 of the Code. Standard 1.5.2 also provides a GM food that is permitted for use as a food additive by Standard 1.3.1 or as a processing aid by Standard 1.3.3 is also a permitted GM food for the purposes of Standard 1.5.2.

Labelling

Standard 1.1.1 requires that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Section 1.5.2—4 requires a food for sale that consists of, or has as an ingredient, a food that is a *genetically modified food* to be labelled as 'genetically modified'[5].

A genetically modified food is a GM food that:

- contains novel DNA or novel protein; or
- is listed in subsections S26—3(2), (2A) and (3) (ie, regardless of the presence of novel DNA or novel protein in the foods). The foods listed in these subsections are considered to have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not produced using gene technology.

Section 1.5.2—4 also provides that its labelling requirement does not apply if the genetically modified food:

- has been highly refined (other than food that has an altered characteristic), where the effect of the refining process is to remove novel DNA or novel protein;
- is a substance used as a processing aid or a food additive and no novel DNA or novel protein from the substance remains present in the food for sale;
- is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%); or
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient; or
- is intended for immediate consumption and is prepared and sold from food premises and vending vehicles, including restaurants, take away outlets, caterers or self-catering institutions.

The labelling requirements imposed by section 1.5.2—4 apply to the following in accordance with Standard 1.2.1:

- a food for retail sale. In the case where a food for retail sale is not required by the Code to bear a label and is not in a package, subsections 1.2.1—9(2) and (3) require labelling information in section 1.5.2—4 to accompany the food or be displayed in connection with the display of the food; or
- a food sold to a caterer. In the case where a food sold to a caterer is not required by the Code to bear a label, section 1.2.1—13 and paragraph 1.2.1—15(f) require information in section 1.5.2—4 to be provided to the caterer with the food.

[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*).

1.4 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

For reasons set out in this report, the draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 23 January 2024. The consultation period was six weeks.

Four submissions were received. Two of these – from New Zealand Food Safety (NZFS) and New Zealand Food and Grocery Council (NZFGC) – supported the proposed draft variation to Schedule 26, and did not raise any issues. The other two submissions, from private individuals, opposed the proposed draft variation and raised a number of issues. Some of the issues were outside the scope of FSANZ's regulatory remit, including general GM issues not directly related to FSANZ's food safety assessment.

Responses to safety issues raised are provided in Table 2.

Table 2: Summary of issues

Issue	Raised by	FSANZ response
Genetic modification results in a depletion of nutrients compared to non-GM foods of the same type.	Private submitter (C.T)	The assessment of DP910521 included a detailed compositional analysis that compared the levels of key constituents in DP910521 to those in conventional non-GM corn cultivars. The data showed there were no biologically significant differences in the composition of DP910521 and non-GM corn. Refer to section 5.3 of the safety assessment report (SD1) for further detail. Over the last 25 years, FSANZ has assessed compositional data for a large array of GM foods and has not observed any trend in nutrient depletion between the GM food and the non-GM counterpart food.

Issue	Raised by	FSANZ response
The allergic or toxic effects of this GM corn in humans are not known.	Private submitter (C.T)	The only difference between corn line DP910521 and non-GM corn is the presence of three novel proteins. The three novel proteins have been assessed for potential allergenicity and toxicity as part of the safety assessment. FSANZ has concluded that none of these proteins are toxic or allergenic to humans. Two of the novel proteins (PAT and PMI) have a long history of safe human consumption, and the third novel protein (Cry1b.34) belongs to a family of proteins (the Cry proteins) that also have a long history of safe human consumption. Refer to section 4 of the safety assessment report (SD1) for further detail. Additional information about FSANZ's safety assessment of GM foods is available on the FSANZ website[6].
Concern about the presence of toxic herbicides in foods derived from this GM corn.	Private submitter (C.T)	Glufosinate-tolerant GM plants, including corn, have been in commercial use since the 1990s. The herbicide metabolites produced in both GM and non-GM plant species sprayed with glufosinate are common across species and are well characterised. The presence of herbicide and herbicide metabolite residues is addressed through the maximum residue limit (MRL) setting process in Australia and New Zealand. FSANZ and the Australian Pesticides and Veterinary Medicines Authority (APVMA) have shared responsibilities for MRLs for food in Australia. For food sold in New Zealand, MRLs are established by the Ministry for Primary Industries. Food sold in Australia must not contain levels of agricultural chemical residues above the relevant MRL. MRLs are listed in Schedule 20[7] of the Code, and are established for all foods, whether or not a product or commodity is GM or non-GM. Australia uses internationally agreed methodologies for establishing MRLs, including consumer dietary exposure estimates to pesticides. The APVMA undertakes a dietary exposure evaluation to ensure that the pesticide levels below the MRL do not pose an undue hazard to human health. The process and data requirements required by the APVMA in setting MRLs are provided on their website[8]. For further details about MRLs please visit the FSANZ website[9] or the NZ MPI website[10].
Concern about the risk of buying byproducts of modified corn in the form of other foodstuffs.	Private submitter (C.T)	No safety concerns have been identified for the consumption of corn line DP910521, including when byproducts are present as ingredients in other foods. Existing labelling requirements for genetically modified foods will apply to food derived from corn line DP910521 to enable informed consumer choice as described in section 2.3.2 of this report. Australian and New Zealand regulators established the National

[6] https://www.foodstandards.gov.au/consumer/gmfood/safety
[7] https://www.legislation.gov.au/F2015L00468/latest/text
[8] https://www.apvma.gov.au/chemicals-and-products/pesticides-and-veterinary-residues
[9] https://www.foodstandards.gov.au/consumer/chemicals/maxresidue
[10] www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/maximum-residue-levels-for-agricultural-compounds/

Issue	Raised by	FSANZ response
		Compliance and Monitoring Strategy of GM Foods[11] in 2010 for the purpose of enabling consistent and effective monitoring and surveillance of GM foods for sale. Further information about GM food labelling is available on the FSANZ website[12].

2.2 Safety assessment

The safety assessment of corn line DP910521 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 DP910521 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 DP910521, or any risks to animals that may consume feed derived from corn line DP910521. Cultivation in Australia or New Zealand would require separate regulatory assessment and approval by the Gene Technology Regulator (GTR)[13] in Australia and the Environmental Protection Authority (EPA)[14] 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 DP910521 is considered to be as safe for human consumption as food derived from non-GM corn varieties.

2.3 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation for a period of six weeks.

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[11] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-National-Compliance-and-Monitoring-Strategy-of-GM-Foods

[12] https://www.foodstandards.gov.au/consumer/gmfood/labelling

[13] 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.*

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

The risk management options available to FSANZ following the call for submissions are to either:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

Following the call of submissions and having regard to the 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 DP910521 is a GM food for Code purposes as it is developed from 'an organism which has been modified by gene technology'[15]. The approved draft variation will list corn line DP910521 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 DP910521 as a GM food in accordance with the Code.

Subject to and in accordance with the draft variation, food derived from corn line DP910521 may enter the Australian and New Zealand food supplies as imported food products. These may include starch, grits, meal, flour, oil and sweetener products.

Cultivation of corn line DP910521 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 DP910521 will require labelling 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 DP910521 does not have altered characteristics (see sections 5 and 6 of SD1).

Refined products from corn line DP910521 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 DP910521 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

[15] ***Food produced using gene technology*** is defined in subsection 1.1.2—2(3) of the Code as 'a food which has been derived or developed from an organism which has been modified by gene technology'.

exemptions listed in subsection 1.5.2—4(1) 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 required statement may be included in the statement of ingredients (subsection 1.5.2—4(3)).

2.3.3 Detection methodology

An Expert Advisory Group (EAG) comprising laboratory personnel and representatives of Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee[16] 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 PCR[17]-based detection method. This sequence information was supplied by the applicant for A1281.

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 released for public comment between 23 January 2024 and 5 March 2024. 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 by FSANZ as part of the decision making process. All comments are valued and contribute to the rigour of our assessment.

Documents relating to A1281, including the submissions received, are available on the FSANZ website[18].

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

[16] Now known as the Implementation Subcommittee for Food Regulation.

[17] Polymerase Chain Reaction.

[18] https://www.foodstandards.gov.au/food-standards-code/applications/a1281-food-derived-herbicide-tolerant-and-insect-protected-corn

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)[19]. 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 (updated OIA reference: **OIA23-06225)**. This is because applications relating to permitting the use of GM foods that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation 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)).

The purpose of this consideration was 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 considered permitting the sale and use of food derived from corn line DP910521.

The consideration of the costs and benefits in this section was 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 sought to highlight the potential positives and negatives of moving away from the status quo by permitting the sale and use of food derived from corn line DP910521.

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

Costs and benefits of permitting the sale and use of food derived from corn line DP910521

The sale and use of foods derived from corn line DP910521 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 DP910521, 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 DP910521 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 will arise from permitting the sale and use of food derived from corn line DP910521 most likely outweigh the associated costs. No further information was received

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

during the consultation process that changed that assessment.

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

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

2.5.1.4 Any other relevant matters

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

The applicant has submitted applications for regulatory approval of corn line DP910521 to other countries, listed in Table 3.

Table 3: List of countries to whom applications for regulatory approval of DP910521 have been submitted

Country	Authority	Type of approval sought	Status
Argentina	National Advisory Commission on Agricultural Biotechnology (CONABIA); National Service of Agri-Food Health and Quality (SENASA)	Food, Feed and Environment	Submitted
Brazil	National Technical Commission on Biosafety (CTNBio)	Food	Approved
Canada	Canadian Food Inspection Agency (CFIA)	Feed and Environment	Submitted
	Health Canada (HC)	Food	Submitted
Columbia	National Institute for the Surveillance of Food and Medicines (INVIMA)	Food	Approved
	Columbian Institute for Agriculture and Livestock (ICA)	Feed	Approved
European Union	European Food Safety Authority (EFSA)	Food and Feed	Submitted
Japan	Ministry of Health, Labour and Welfare (MHLW)	Food	Approved
	Ministry of Agriculture, Forestry and Fisheries	Feed	Submitted
Malaysia	Ministry of Natural Resources, Environment and Climate Change (NRECC)	Food and Feed	Submitted
Taiwan	Ministry of Health and Welfare (MOHW) / Taiwan Food and Drug Administration (TFDA)	Food	Submitted
Uruguay	Ministry of Livestock, Agriculture and Fisheries (MGAP)/Biosafety Cabinet (GNBio)	Food, Feed, Environment	Submitted
United States	Food and Drug Administration (FDA)	Food and Feed	Approved
	United States Department of Agriculture (USDA)	Environment	Submitted
	Environmental Protection Agency (EPA)	Environment	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 DP910521. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from corn line DP910521 is as safe for human consumption as food derived from conventional non-GM corn varieties.

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 DP910521 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) addresses this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2009). Based on these principles, the risk analysis undertaken by FSANZ for corn line DP910521 used the best scientific evidence available. The applicant submitted a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the applicant, other available resource material including published scientific literature and general technical information was used by FSANZ in the safety assessment.

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

There are no relevant international standards.

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

The inclusion of GM foods in the food supply, providing there are no safety concerns, allows for innovation by developers and a widening of the technological base for producing foods. Corn line DP910521 is a new food crop designed for tolerance to the herbicide glufosinate and to provide growers with an additional control option for lepidopteran insect pests, including fall armyworm.

- **the promotion of fair trading in food**

Issues related to consumer information and safety are considered in sections 2.2 and 2.3 above.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

No specific policy guidelines have been developed.

3 Draft variation

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

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

4 References

Codex (2009) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome. http://www.fao.org/3/a1554e/a1554e00.htm

Attachments

A. Approved draft variation to the Australia New Zealand Food Standards Code
B. Explanatory Statement

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

Food Standards (Application A1281 – Food derived from herbicide-tolerant and insect-protected corn line DP910521) 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]

[Insert name and position of the delegate]
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 A1281 – Food derived from herbicide-tolerant and insect-protected corn line DP910521) 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:

(zj) herbicide-tolerant and insect-protected corn line DP910521

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1281 – Food derived from herbicide-tolerant and insect-protected corn line DP910521) 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 A1281 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 DP910521. Corn line DP910521 has been genetically modified for tolerance to the herbicide glufosinate and protection from lepidopteran insect pests, including fall armyworm. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards (Application A1281 – Food derived from herbicide-tolerant and insect-protected corn line DP910521) 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 sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the

international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation amending the table to subsection S26—3(4) in Schedule 26 of the Code to permit the sale and use of food derived from a new GM food – corn line DP910521, in accordance with the Code. Corn line DP910521 has been genetically modified for tolerance to the herbicide glufosinate and protection from lepidopteran 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 A1281 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 23 January 2024 for a six-week consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[20]. 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, updated OIA reference: **OIA23-06225**. This is because applications relating to permitting the use of GM foods that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation relating to the application is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

6. Statement of compatibility with human rights

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

7. Variation

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1281 – Food derived from herbicide-tolerant and insect-protected corn line DP910521) 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.

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

Item [1] of the Schedule to the variation amends Schedule 26 by inserting, in alphabetical order, a new paragraph '(zj)' 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 (zj) refers to 'herbicide-tolerant and insect-protected corn line DP910521'.

The effect of this amendment is to permit the sale and use of food derived from corn line DP910521 in accordance with the Code.