1 October 2020
[136–20]

Call for submissions – Application A1202

Food derived from herbicide-tolerant and insect-protected corn line DP23211

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Dow AgroSciences Australia Pty Ltd seeking to permit the sale and use of food derived from genetically modified (GM) corn line DP23211, which has tolerance to the herbicide glufosinate and is protected against corn rootworm insect pests. A draft food regulatory measure has been prepared. Pursuant to section 31 of the Food Standards Australia New Zealand Act 1991 (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft variation.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

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

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 12 November 2020

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

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

Table of contents

Supporting document

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

SD1 Safety Assessment Report

[1] https://www.foodstandards.gov.au/code/applications/Pages/A1202.aspx

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Dow AgroSciences Australia Pty Ltd to request a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to permit the sale and use of food derived from genetically modified (GM) corn line DP23211 that has tolerance to the herbicide glufosinate and is protected against the insect pest, 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* (FSANZ Act), is the protection of public health and safety. Accordingly, the safety assessment is a central part of considering an application.

The safety assessment of corn line DP23211 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 DP23211 is considered to be as safe for human consumption as food derived from conventional non-GM corn cultivars.

FSANZ has prepared a draft variation to Schedule 26 of the Code that includes a reference to food derived from corn line DP23211. The effect of the draft variation will be to permit the use or sale of food derived from this corn line in accordance with Standard 1.5.2 of the Code.

1 Introduction

1.1 The applicant

Dow AgroSciences Australia Pty Ltd is a member of Corteva Agriscience group of companies and is a technology provider to a number of sectors including the agriculture sector.

1.2 The application

Application A1202 was submitted on 23 March 2020. It seeks approval for the sale and use of food derived from corn line DP23211 that has tolerance to the herbicide glufosinate and is protected against the insect pest, corn rootworm.

Tolerance to the herbicide glufosinate is achieved by the expression of the maize-optimised *mo-pat* gene, derived from the bacterium *Streptomyces viridochromogenes*, encoding the enzyme phosphinothricin acetyltransferase (PAT). Protection against corn rootworm is conferred by the expression in the plant of two novel substances: the IPD072Aa protein (encoded by the *ipd072Aa* gene) from soil bacterium *Pseudomonas chlororaphis* and DvSSJ1, a double stranded ribonucleic acid (dsRNA) that specifically silences the corn rootworm *dvssj1* gene via RNA interference (RNAi). These novel substances cause intestinal epithelium damage specifically in corn rootworm larvae. DP23211 also expresses the phosphomannose isomerase (PMI) protein from *Escherichia coli* strain K-12 as a selectable marker. While the PAT and PMI proteins have been assessed previously by FSANZ, this is the first application to assess the IPD072Aa protein and DvSSJ1 dsRNA.

Food derived from corn line DP23211 may enter the Australian and New Zealand food supply as imported food products. These may include starch, grits, meal, flour, oil and sweetener products. Fresh whole corn cob will not be allowed for sale in Australia and New Zealand without a prior assessment and approval by the Gene Technology Regulator in Australia and the Environmental Protection Authority (EPA) in New Zealand. Corn cob containing seeds would be considered a viable genetically modified organism.

1.3 The current standard

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

Section 1.5.2—4 of the Code requires food to be labelled as ‘genetically modified’ where novel DNA and/or novel protein remains present in the final food. The requirement applies to foods for sale that consist of, or have as an ingredient (including food additives and processing aids from GM sources), food that is a GM food. Standard 1.2.1 provides that the requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer - see subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

Foods listed in subsections S26—3(2), (2A) and (3) of Schedule 26 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. Foods listed in these subsections 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.

The requirement to label food as ‘genetically modified’ does not apply to food that:

- has been highly refined (other than food that has been altered), 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 final food
- is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%)
- is intended for immediate consumption and which is prepared and sold from food premises and vending machines, including restaurants, take away outlets, caterers, or self-catering institutions
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient.

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

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

1.4 Reasons for accepting application

The application was accepted for assessment because:

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

1.5 Procedure for assessment

The application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Safety assessment

The safety assessment of corn line DP23211 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
- the potential for any newly expressed protein to be either allergenic or toxic in humans.

In conducting the safety assessment, FSANZ had regard to 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 other applications.

The assessment of corn line DP23211 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 GM plants used in food production, or any risks to animals that may consume feed derived from GM plants. Cultivation in Australia or New Zealand would require separate regulatory assessment and approval, by the Gene Technology Regulator in Australia and by the EPA in New Zealand.

No potential public health and safety concerns have been identified.

Based on the data provided in the present application, and other available information, food derived from corn line DP23211 is considered to be as safe for human consumption as food derived from non-GM corn cultivars.

2.2 Risk management

2.2.1 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food derived from DP23211 would be required to be labelled as 'genetically modified' if it: contains novel DNA or novel protein; or is listed in subsections S26—3(2), (2A) and (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 DP23211 does not have altered characteristics.

The grain from commercial lines derived from DP23211 may be used to produce wet-milled starch for sweetener products, maize oil and high fructose corn syrup (HFCS). In Australia and New Zealand, maize starch is used in dessert mixes and canned food products and HFCS is used in breakfast cereals, baking products, extruded confectionary and corn chips. DP23211 is a corn line that could be used as a parent in the development of sweet corn lines.

Refined products from DP23211 such as maize starch, maize oil and HFCS are unlikely to contain any novel protein or novel DNA and would unlikely require labelling as 'genetically modified'.

DP23211 products such as meal (used in bread and polenta) and grits (used in cereals) would likely contain novel protein or novel DNA, and if so, would require labelling as 'genetically modified'. Sweet corn kernels from DP23211 imported for sale in Australia and New Zealand, are also likely to trigger labelling requirements.

The requirements for labelling as 'genetically modified' differ depending on whether the GM food is an ingredient of the food for sale or not. For example, corn meal derived from DP23211 that is sold at retail would require the labelling statement.

However, FSANZ notes DP23211 products may be used to manufacture a food that is not itself a food for sale, but is used as an ingredient in foods for retail sale or in food sold to a caterer (for example, corn meal derived from DP23211 is used to make a crumbed fish and the crumbed fish is then used as an ingredient in a 'ready meal'). As such, these ingredients are not GM foods and are not subject to labelling requirements set out in section 1.5.2—4.

2.2.2 Detection methodology

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee[2] to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food

[2] Now known as the Implementation Subcommittee for Food Regulation

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-based detection method. This sequence information was supplied by the applicant for A1202.

2.3 Risk communication

2.3.1 Consultation

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

FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, media release, through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received on this call for submissions.

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

2.3.2 World Trade Organization (WTO)

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

There are no relevant international standards and amending the Code to permit food derived from corn line DP23211 is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

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

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

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application). This analysis considers permitting food from corn line DP23211.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting food derived from DP23211. FSANZ is of the view that no other realistic food regulatory measures exist, however information received through the consultation process may result in FSANZ arriving at a different conclusion.

Costs and benefits of permitting food derived from DP23211

Foods derived from DP23211 would be permitted under the Code, allowing broader market access and increased choice in raw materials. For those DP23211 food products containing novel DNA or novel protein, required labelling would allow consumers wishing to avoid these products to do so.

Due to the voluntary nature of the permission, manufacturers and retailers will only engage with corn line DP23211 where they believe a net benefit exists.

Part of any cost savings to industry may be passed onto consumers.

There may be small and likely inconsequential costs of monitoring an extra GM food ingredient for regulators to ensure compliance with labelling requirements.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting food derived from corn line DP23211 most likely outweigh the associated costs.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than varying Schedule 26 as a result of application A1202.

2.4.1.3 Any relevant New Zealand standards

Standard 1.5.2 and Schedule 26 apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.4.1.4 Any other relevant matters

The applicant has submitted applications for regulatory approval of corn line DP23211 to a number of other countries, as listed in Table 1.

The applicant has stated they currently have no intention to apply for approval to cultivate corn line DP23211 in Australia. Cultivation in Australia or New Zealand would require independent assessment and approval by the Gene Technology Regulator and NZ EPA,

respectively.

Table 1: List of countries to whom applications for regulatory approval of DP23211 have been submitted

Country	Agency	Type of approval sought	Status
European Union	European Food Safety Authority	Food and feed	Submitted

Further other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

Food derived from corn line DP23211 has been assessed based on the data requirements provided in the FSANZ *Application Handbook*[3] which, in turn reflect internationally-accepted GM food safety assessment guidelines. No public health and safety concerns were identified in this assessment. Based on the available evidence, including detailed studies provided by the applicant, food derived from corn line DP23211 is considered as safe as food derived from other non-GM corn lines.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

To enable informed consumer choice the existing requirements for GM labelling will apply to food derived from corn line DP23211 (see Section 2.2.1 of this Report).

2.4.2.3 The prevention of misleading or deceptive conduct

The provision of detection methodology by the applicant (as described in Section 2.2.2) addresses this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2009). Based on these principles, the risk analysis undertaken for DP23211 used the best scientific evidence available. The applicant submitted a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the applicant, other available resource material including published scientific literature and general technical information was used in the safety assessment.

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

[3] http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx

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 DP23211 is a new food crop designed to provide growers with an additional control option for corn rootworm pests, as well as a herbicide-tolerance option for corn farming systems.

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

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

- **any written policy guidelines formulated by the Forum on Food Regulation**

No specific policy guidelines have been developed.

3 Draft variation

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

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

4 References

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

Attachments

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

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

Food Standards (Application A1202 – Food derived from herbicide-tolerant and insect-protected corn line DP23211) 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]

Scott Crerar
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 A1202 – Food derived from herbicide-tolerant and insect-protected corn line DP23211) 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

[1] Schedule 26 is varied by inserting in the table to subsection S26—3(4) in alphabetical order under item 2

(zd) herbicide-tolerant and insect-protected corn line DP23211

Attachment B – Draft Explanatory Statement

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 A1202 which seeks approval for food derived from herbicide-tolerant and insect-protected corn line DP23211. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The purpose of the draft variation is to permit the sale and use of food derived from genetically modified corn line DP23211.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1202 will include one round of public consultation following an assessment and the preparation of a draft variation. A call for submissions (including the draft variation) will occur for a six-week consultation period.

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010, granted a standing exemption from the need for the OBPR to assess if a Regulatory Impact Statement is required for the approval of genetically modified foods (ref 12065). This standing exemption was provided as varying Schedule 26 is a consequential change of maintaining a permitted schedule of GM foods. Additionally, permitting new GM foods is deregulatory as using the GM technology will be voluntary if the Application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe. As such, a Regulation Impact Statement was not required in this case as the sale or use of food derived from corn line DP23211, if approved, would be voluntary and would be likely to have a minor impact on business and individuals.

5. 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 94 of the FSANZ Act.

6. Variation

Item [1] amends Schedule 26 by inserting new paragraph (zd) into item 2 in the table to subsection S26—3(4) in Schedule 26. The new paragraph refers to herbicide-tolerant and insect-protected corn line DP23211. The effect of the variation is to permit the sale and use of food derived from that corn line in accordance with Standard 1.5.2.