

**9 February 2021**  
**150-21**

## **Approval report – Application A1202**

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

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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 a food produced using gene technology: corn line DP23211. This corn line has been genetically modified for tolerance to the herbicide glufosinate and is protected against corn rootworm insect pests.

On 1 October 2020, FSANZ sought [submissions](#) on a draft to Schedule 26 and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 3 February 2021. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 5 February 2021.

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

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### Supporting document

The following document which informed the assessment of this application is available on the [FSANZ website](https://www.foodstandards.gov.au/code/applications/Pages/A1202.aspx)<sup>1</sup>:

SD1        Supporting document 1 (safety assessment)

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<sup>1</sup> <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 a new food produced using gene technology (GM food): corn line DP23211. Corn line DP23211 has been genetically modified for 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 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.

Existing labelling requirements for GM food will apply to food derived from corn line DP23211 in accordance with the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 1 October 2020. Two submissions were received, both of which FSANZ has had regard to (see Section 2.1 of this report for a summary of submissions made and FSANZ's responses to those submissions).

FSANZ has decided to approve the draft variation proposed following assessment without change. The draft variation amends Schedule 26 of the Code by inserting a reference to 'herbicide-tolerant and insect-protected corn line DP23211' in the table to subsection S26—3(4). The effect of the draft variation is to permit the use and sale of food derived from this corn line in accordance with the Code.

# 1 Introduction

## 1.1 The applicant

Dow AgroSciences Australia Pty Ltd<sup>2</sup> is a member of the Corteva Agriscience group of companies and is a technology provider to the agriculture sector.

## 1.2 The application

Application A1202 was submitted by Dow AgroSciences Australia Pty Ltd 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 and was used as a selectable marker following plant transformation. While the PAT and PMI proteins have been assessed previously by FSANZ, this is the first application in which FSANZ has assessed 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. Corn cob containing seeds would be considered a viable genetically modified organism, and therefore, 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.

## 1.3 The current standard

Pre-market approval is necessary before a food produced using gene technology (a GM food) 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 GM food. Foods that have been assessed and approved are listed in Schedule 26 of the Australia New Zealand Food Standards Code (the Code).

Subject to certain exceptions listed below, section 1.5.2—4 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), food that is a *genetically modified food*<sup>3</sup>. Standard 1.2.1

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<sup>2</sup> Dow AgroSciences Australia Pty Ltd officially changed its name in Australia to Corteva Agriscience Australia Pty Ltd on 6 January 2021. FSANZ was informed of this change on 7 January 2021.

<sup>3</sup> Section 1.5.2—4(5) defines **genetically modified food** to mean a \*food produced using gene technology that

- contains novel DNA or novel protein; or
- 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*).

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 labelling requirement in section 1.5.2—4 does not apply if the genetically modified food:

- 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; or
- 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; or
- 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 machines, including restaurants, take away outlets, caterers, or self-catering institutions.

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 the application**

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (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 was assessed under the General Procedure.

## 1.6 Decision

The draft variation as proposed following assessment was approved without change. The approved draft 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 assessment

### 2.1 Summary of issues raised in submissions

FSANZ called for submissions (CFS) on a proposed draft variation on 1 October 2020.

A total of two submissions were received, of which both supported the proposed draft variation to Schedule 26. These were from:

- Victorian Department of Health and Human Services (DHHS) and the Victorian Department of Jobs, Precincts and Regions (DJPR)
- New Zealand Food Safety (NZFS).

In their submission, NZFS provided a few comments including specific comments in consultation with the Institute of Environmental Science and Research Limited (ESR). These have been addressed in the Summary of Issues (Table 1).

**Table 1: Summary of Issues**

Issue	Raised by	FSANZ response
Potential spray residue levels in DP23211 crops compared to non-tolerant/non-GM crops were not covered in the assessment	NZFS	The presence of herbicide and herbicide metabolite residues is addressed through the maximum residue limit (MRL) setting process in Australia and New Zealand. MRLs are for all foods, regardless of whether the product or commodity is GM or non-GM. Food sold in Australia must not contain levels of agricultural chemical residues above the MRLs. MRLs are listed in Schedule 20 of the <a href="#">Australia New Zealand Food Standards Code</a> <sup>4</sup> . For food sold in New Zealand, MRLs are established by the Ministry for Primary Industries. FSANZ notes that glufosinate-tolerant GM plants have been in commercial use since the 1990s, including GM corn. The herbicide metabolites produced in both GM and non-GM plant species sprayed with glufosinate are common across species and are well characterised. As stated in Section 4.3 of Supporting Document 1, due to the history of use "It is expected that no new glufosinate metabolites would be generated in corn event DP23211".
An acute oral toxicity study of IPD072Aa in mice would have been improved by using additional higher doses. No guideline is	ESR/NZFS	The available acute toxicity study conducted according to the OECD guideline <sup>5</sup> confirmed the results of the safety assessment. As described in Section 4.1.3.3 of the Supporting Document 1, no treatment-related adverse effects were observed at the 2000 mg/kg body weight oral dose of IPD072Aa. IPD072Aa was susceptible to pepsin and pancreatin digestion and bioinformatic analyses showed IPD072Aa had no homology to known toxins and allergens. The evidence presented in Supporting Document 1 supports the conclusion that IPD072Aa is not

<sup>4</sup> [www.foodstandards.gov.au/code/Pages/default.aspx](http://www.foodstandards.gov.au/code/Pages/default.aspx)

<sup>5</sup> [https://www.oecd-ilibrary.org/environment/test-no-423-acute-oral-toxicity-acute-toxic-class-method\\_9789264071001-en](https://www.oecd-ilibrary.org/environment/test-no-423-acute-oral-toxicity-acute-toxic-class-method_9789264071001-en)

Issue	Raised by	FSANZ response
referenced in the applicant's assessment on acute toxicity tests		toxic or allergenic in humans.  In the absence of any identifiable hazard, FSANZ does not consider higher doses in an acute oral toxicity study are justified.

## 2.2 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 corn line DP23211, or any risks to animals that may consume feed derived from corn line DP23211. 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 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.

## 2.3 Risk management

### 2.3.1 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food for sale derived from corn line DP23211 would be required to be labelled as 'genetically modified' if (among other things) the GM food:

- contains novel DNA or novel protein; or
- is listed in subsection S26—3(2), (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 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 will unlikely require labelling as 'genetically modified'.

DP23211 products such as meal (used in bread and polenta) and grits (used in cereals) will likely contain novel protein or novel DNA, and will therefore likely require labelling as 'genetically modified'. Sweet corn kernels from DP23211 imported for sale in Australia and New Zealand, will also likely 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 will likely 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, the ingredients in the food for sale are not GM foods and are not subject to labelling requirements set out in section 1.5.2—4.

### **2.3.2 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<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 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.

## **2.4 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 are requested to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

Public submissions were invited on a draft variation which was released for public comment between 1 October 2020 and 12 November 2020. The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media tools and the publication, Food Standards News. Subscribers and interested parties were also notified.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission on this application was considered by FSANZ. All

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

comments are valued and contribute to the rigour of the safety assessment.

Documents relating to Application A1202, including submissions received, are available on the [FSANZ website](#)<sup>7</sup>.

#### **2.4.2 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 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.

### **2.5 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**

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 because varying Schedule 26 of the Code is a consequential change of maintaining a permitted schedule of GM foods. Additionally, permitting a new GM food is deregulatory as using the gene technology will be voluntary if the application concerned is approved. The standing exemption relates to the introduction of a food to the food supply that is voluntary and has been determined to be safe.

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 food from corn line DP23211. No further information was received during the consultation process that changed the findings from the analysis of costs and benefits in the CFS.

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

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<sup>7</sup> <https://www.foodstandards.gov.au/code/applications/Pages/A1202.aspx>

assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting food derived from DP23211.

FSANZ's assessment was that the direct and indirect benefits that would arise from permitting food derived from corn line DP23211 most likely outweigh the associated costs. Due to the voluntary nature of the permission, manufacturers and retailers will only use produce from corn line DP23211 where they believe a net benefit exists. Part of any cost savings to industry may be passed onto consumers. For those DP23211 food products containing novel DNA or novel protein, required labelling will allow consumers wishing to avoid these products to do so. There may be small and likely inconsequential costs of monitoring an extra GM food ingredient for regulators to ensure compliance with labelling requirements.

### **2.5.1.2 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.

### **2.5.1.3 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.

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

The applicant has submitted applications for regulatory approval of corn line DP23211 to countries listed in Table 1.

The applicant has stated they currently have no intention 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
United States of America	United States Department of Agriculture	Commercial cultivation	Submitted

Further other relevant matters are considered below.

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

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

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

Food derived from corn line DP23211 has been assessed based on the data requirements provided in the FSANZ [Application Handbook](#)<sup>8</sup> which, in turn reflect internationally-accepted GM food safety assessment guidelines. No public health and safety concerns were identified

<sup>8</sup> <http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

in this assessment. Based on the available evidence, including detailed studies provided by the applicant, food derived from corn line DP23211 is considered to be as safe for human consumption as food derived from non-GM corn lines.

#### **2.5.2.2 *The provision of adequate information relating to food to enable consumers to make informed choices***

To enable informed consumer choice the existing labelling requirements for GM food will apply to food derived from corn line DP23211 in accordance with the Code (see Section 2.3.1 of this Report).

#### **2.5.2.3 *The prevention of misleading or deceptive conduct***

The provision of DNA sequence information by the applicant (as described in Section 2.3.2) 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 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**

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 approved 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. 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 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]

[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 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 – 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 to permit the sale and use of food derived from corn line DP23211 as a new food produced using gene technology (a GM food). Corn line DP23211 has been genetically modified for tolerance to the herbicide glufosinate and is protected against the insect pest, corn rootworm. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

### **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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report.

The Office of Best Practice Regulation (OBPR) granted the Authority 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 because varying Schedule 26 is a consequential change of maintaining a permitted schedule of GM foods. Additionally, permitting a new GM food is deregulatory as using the gene technology will be voluntary if the Application concerned is approved. The standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

### **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 of the table to subsection S26—3(4) in Schedule 26 in alphabetical order.

The new paragraph refers to ‘herbicide-tolerant and insect-protected corn line DP23211’. Corn line DP23211 is a corn line genetically modified for tolerance to the herbicide glufosinate and is protected against the insect pest, corn rootworm.

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