

**15 December 2020**  
**[145-20]**

## **Approval report – Application A1198**

### **Food derived from enhanced yield & herbicide-tolerant corn line DP202216**

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Food Standards Australia New Zealand (FSANZ) has assessed an application from Dow AgroSciences Australia Pty Ltd to permit the use of corn line DP202216 as a new food produced using gene technology and has prepared a draft food regulatory measure. This corn line has been genetically modified for enhanced yield and herbicide-tolerance to glufosinate.

On 6 August 2020, FSANZ sought [submissions](#) on a draft variation and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation on 1 December 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 15 December 2020.

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:

SD1 – Safety Assessment report

## Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Dow AgroSciences Australia Pty Ltd requesting 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: corn line DP202216. This corn line has been genetically modified for enhanced yield and herbicide-tolerance to glufosinate.

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 DP202216 is in Supporting Document 1 (SD1). No potential public health and safety concerns were identified. Based on the data provided and other information, food derived from corn line DP202216 is considered to be as safe for human consumption as food derived from conventional corn cultivars (non-genetically modified (GM) corn cultivars). Current labelling requirements for GM food will apply to foods for sale that consist of, or have as an ingredient, food that is GM food.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 6 August 2020. A total of six submissions were received, all 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 to include a reference to 'enhanced yield and herbicide-tolerant corn line DP202216'. The effect of the draft variation will be to permit the sale and use of food derived from that corn line in accordance with the Code.

# 1 Introduction

## 1.1 The Applicant

Dow AgroSciences Australia Pty Ltd is a technology provider to a number of sectors including the agriculture sector.

## 1.2 The Application

Application A1198 was submitted on 9 December 2019. It seeks 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 corn line produced using gene technology: corn line, DP202216. This corn line has been genetically modified for enhanced yield and herbicide-tolerance to glufosinate.

Enhanced yield is achieved through increased expression of an endogenous gene *zmm28*, which encodes a transcription factor (ZMM28) that regulates the expression of genes associated with floral organ development. 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). While the PAT protein has been assessed previously by FSANZ, this is the first application to assess the ZMM28 protein.

The applicant has indicated the type of food products derived from DP202216 would be wet-milled starch for sweetening products, maize oil and high fructose corn syrup (HFCS). In Australia and New Zealand, maize starch is used in dessert mixes and canned foods and HFCS is used in breakfast cereals, baking products, corn chips and extruded confectionary. 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 (Australia) and the Environmental Protection Authority (New Zealand), respectively. Corn cob containing seeds would be considered a viable genetically modified organism. However, the applicant has stated they currently have no intention to apply for approval to cultivate DP202216 in Australia and New Zealand. Therefore food from DP202216 may only be present in the Australian and New Zealand food supply via imported products.

## 1.3 The current Standard

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

Section 1.5.2—4 of Standard 1.5.2 also contains labelling provisions for 'genetically modified food'. A 'genetically modified food' is defined to mean a GM food that either contains novel DNA or novel protein; or is listed in section S26—3 as being subject to the condition that its labelling must comply with that section (see subsection 1.5.2—4(5)). Subject to certain exceptions listed below, genetically modified foods and ingredients (including food additives and processing aids from GM sources) must be identified on labels with the words 'genetically modified', if novel DNA or novel protein (as defined in Standard 1.5.2) is present in the 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 GM 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 was assessed under the General Procedure.

## **1.6 Decision**

The draft variation as proposed following assessment was approved without change. The variation takes effect on 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 received a total of six submissions. Submissions that supported the proposed draft variation were received from:

- New Zealand Food and Grocery Council (NZFGC)
- New Zealand Ministry for Primary Industries (MPI)
- Victorian Department of Health and Human Services and Victorian Department of Jobs, Precincts and Regions (VicHealth).

MPI requested some additional information about increased exposure to the novel protein ZMM28 and the herbicide and herbicide metabolites, which has been addressed in the Summary of Issues (Table 1).

Submissions opposing the draft variation were received from three private individuals. These individuals raised general concerns about GM foods including their safety, labelling and the presence of herbicides. These issues have been addressed in Table 1.

Included in the three opposing submissions were issues outside the scope of FSANZ's regulatory framework. For example social impact of processed foods, environmental issues from pesticide use, and broader GM issues unrelated to this application.

**Table 1: Summary of issues**

	Issue	Raised by	FSANZ response
1	Could FSANZ comment on the potential increased dietary exposure to the novel ZMM28 protein.	MPI	<p>As detailed in Sections 4.1.2 of Supporting Document 1 (SD1), the ZMM28 protein is expressed at low but detectable levels in corn grain from DP202216 but not detectable in the non-GM control corn grain.</p> <p>The safety assessment of this protein confirmed ZMM28 does not represent a hazard, therefore any potential increase in dietary exposure would not raise any safety concerns.</p> <p>In addition, the most likely products to be imported into Australia and New Zealand would be highly refined starch, oil and corn syrup. These refined products are unlikely to contain protein.</p>
2	To ensure transparency, all products containing GM ingredients need to be labelled.	AM	<p>Food derived from DP202216 will be required to be labelled as ‘genetically modified’ if it contains novel DNA or novel protein, as outlined and discussed in section 2.3.1 of this Report.</p>
3	There has been insufficient human feeding trials undertaken on this product.	BA	<p>Human feeding trials are not routine requirements of GM food safety assessment and are not required anywhere in the world.</p> <p>The novel proteins expressed in DP202216, ZMM28 and PAT, are already in the human food supply. Both the <i>zmm28</i> gene and protein are present in non-GM corn, including in the majority of sweet corn cultivars.</p> <p>PAT was first introduced into GM food crops in the 1990s and has a 25 year history of safe use in food.</p>
4	Could you clarify the independence of the studies relied upon in the safety assessment, especially when unpublished reports are not available to the public.	GE	<p>An application must meet specific data requirements for FSANZ to undertake the safety assessment. These requirements are listed in the FSANZ Application Handbook<sup>1</sup> (Guideline 3.5.1) and follow internationally agreed guidelines established by Codex.</p> <p>Studies (including raw data) supplied by the applicant were independently assessed by FSANZ to ensure they were of sufficient quality, have been conducted in an appropriate manner, and did not raise concerns regarding the safety of the product. In addition to data submitted by the applicant, FSANZ considered information from a variety of other sources including the scientific literature, general technical information, and information from other regulatory agencies, as well as from international bodies such as the OECD and Codex.</p>

<sup>1</sup> <https://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

	Issue	Raised by	FSANZ response
5	<p>FSANZ did not require a thorough analysis of the herbicide metabolites in this new corn line DP202216.</p> <p>FSANZ also did not consider the presence of herbicide and herbicide metabolite residues in GM foods and potential health impacts on consumers.</p>	BA, GE, MPI	<p>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.</p> <p>As stated in Section 4.4 of Supporting Document 1, due to the history of use “It is expected that no new glufosinate metabolites would be generated in corn event DP202216.”</p> <p>The presence of herbicide and herbicide metabolite residues is addressed through the maximum residue limit (MRL) setting process in Australia and New Zealand.</p> <p>Food sold in Australia must not contain levels of agricultural chemical residues above the maximum residue limits (MRLs). MRLs are listed in Schedules 20 and 21 of the <a href="#">Australia New Zealand Food Standards Code</a><sup>2</sup>. For food sold in New Zealand, MRLs are established by the Ministry for Primary Industries.</p> <p>For MRLs to be established, an assessment is made to consider consumer dietary exposure estimates to pesticides against health based guidance values. MRLs are established for all foods, whether or not a product or commodity is GM or non-GM.</p> <p>For further details about MRLs please visit the FSANZ website <a href="#">Chemicals in Food</a><sup>3</sup> or the NZ MPI website <a href="#">Maximum residue levels (MRLs) for agricultural compounds</a><sup>4</sup>.</p> <p>Further questions related to toxicity of pesticides can also be addressed to the <a href="#">Australian Pesticide and Veterinary Medicine Authority</a><sup>5</sup> in Australia and the <a href="#">Environmental Protection Authority</a><sup>6</sup> in New Zealand.</p>

<sup>2</sup> [www.foodstandards.gov.au/code/Pages/default.aspx](http://www.foodstandards.gov.au/code/Pages/default.aspx)

<sup>3</sup> [www.foodstandards.gov.au/consumer/chemicals/maxresidue/Pages/default.aspx](http://www.foodstandards.gov.au/consumer/chemicals/maxresidue/Pages/default.aspx)

<sup>4</sup> [www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/maximum-residue-levels-for-agricultural-compounds/](http://www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/maximum-residue-levels-for-agricultural-compounds/)

<sup>5</sup> [apvma.gov.au](http://apvma.gov.au)

<sup>6</sup> [www.epa.govt.nz](http://www.epa.govt.nz)

## 2.2 Safety assessment

The safety assessment of DP202216 is provided in SD1.

In conducting a safety assessment of food derived from DP202216, a number of criteria have been addressed, focusing on both the safety of the host corn plant and the genetically modified corn line DP202216, expressing the novel proteins. The safety of DP202216 included a full characterisation of the introduced gene sequences, biochemical, potential toxicity and potential allergenicity analyses of the novel ZMM28 and PAT proteins and compositional analyses. These analyses considered both the intended and any unintended changes resulting from the genetic modification.

The assessment of DP202216 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. The applicant has no intention to apply for commercial cultivation of DP202216 in Australia or New Zealand. Cultivation in Australia would require assessment and approval by the Gene Technology Regulator. Should cultivation in New Zealand be sought, this would require assessment and approval by the Environmental Protection Authority in New Zealand. In both countries, growing the GM corn without appropriate authorisation would be an offence under the respective legislation.

No public health and safety concerns have been identified by the food safety assessment.

Based on the data provided in the application, and other available information, food derived from corn line DP202216 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 derived from DP202216 will 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 DP202216 does not have altered characteristics.

Mature grain obtained from commercial lines derived from DP202216 may be used to produce wet-milled starch for sweetening products, maize oil and 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, corn chips and extruded confectionary. DP202216 is a corn line that could also be used as a parent in the development of sweet corn lines.

Refined products such as corn syrup and corn starch are unlikely to contain any novel protein or novel DNA and will be unlikely to require labelling as 'genetically modified'.

DP202216 products such as meal (used in bread and polenta) and grits (used in cereals) will be likely to contain novel protein or novel DNA, and if so, will require labelling as 'genetically modified'. If there is approval to import sweet corn kernels from DP202216 for sale in

Australia and New Zealand, this product is 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 DP202216 that is sold at retail will require the labelling statement because of the presence of protein.

However, FSANZ notes that DP202216 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 DP202216 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 genetically modified foods and are not subject to labelling requirements set out in section 1.5.2—4(1).

### **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>7</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 A1198.

## **2.4 Risk communication**

### **2.4.1 Consultation**

Consultation is a key part of the FSANZ standards development process.

FSANZ developed and applied a basic 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.

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

Documents relating to Application A1198, including submissions received, are available on the FSANZ website.

### **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.

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<sup>7</sup> Now known as the Implementation Subcommittee for Food Regulation

There are no relevant international standards and amending the Code to permit food derived from DP202216 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 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. 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, 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 the sale and use of food derived from GM corn DP202216.

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 the sale and use of food derived from DP202216. FSANZ is of the view that no other realistic food regulatory measures exist.

#### *Costs and benefits of permitting the sale and use of food derived from GM corn DP202216*

Food containing event DP202216 has been assessed as being as safe as food from non-GM lines of corn.

The sale of foods derived from GM corn DP202216 would be permitted under the Code, allowing broader market access and increased choice in raw materials. For those food products containing novel DP202216, labelling is 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 DP202216, where they believe a net benefit exists for them. Part of any cost savings to industry may be passed onto consumers.

If DP202216 is approved for commercial growing in overseas countries, it could be used to manufacture products using co-mingled corn seed. This means no costs of having to exclude DP202216 seed from co-mingling and hence no consequential need to increase the prices of foods that are manufactured using co-mingled corn seed.

Dow AgroSciences will obtain a financial benefit from permitting the sale and use of food derived from GM corn DP202216 as they own the technology used to generate line DP202216.

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 the sale and use of food derived from GM corn DP202216, most likely outweigh the associated costs.

**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 A1198.

**2.5.1.3 Any relevant New Zealand standards**

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

**2.5.1.4 Any other relevant matters**

The applicant has submitted applications for regulatory approval of DP202216 to a number of other countries, as listed in Table 2.

The applicant has stated they currently have no intention to apply for approval to cultivate DP202216 in Australia and New Zealand. Cultivation in Australia or New Zealand would require independent assessment and approval by the Gene Technology Regulator and NZ EPA respectively.

**Table 2: List of countries to whom applications for regulatory approval of DP202216 have been submitted**

Country	Agency	Type of approval sought	Status
United States of America	Department of Agriculture	Commercial cultivation	Submitted
European Union	European Food Safety Authority	Importation	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 DP202216 has been assessed based on the data requirements provided in the FSANZ [Application Handbook](#)<sup>2</sup> 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 DP202216 is considered as safe as food derived from other commercially available non-GM and GM corn lines.

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

In accordance with existing labelling provisions in the Code, food derived from DP202216 would be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see Section 2.3.1).

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

The provision of sequence by the applicant would allow development of a detection method (as described in Section 2.3.2), which would address 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 DP202216 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 DP202216 is a new food crop designed to provide growers with an enhanced yield and herbicide-tolerance to glufosinate option for corn farming systems.

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

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

## **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 A1198 – Food derived from enhanced yield & herbicide-tolerant corn line DP202216) 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 A1198 – Food derived from enhanced yield & herbicide-tolerant corn line DP202216) 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

(zc) enhanced yield and herbicide-tolerant corn line DP202216

## **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 A1198 which seeks approval for food derived from a new food produced using gene technology: corn line DP202216, genetically modified for enhanced yield and tolerance to glufosinate. 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 Authority has approved the draft variation to permit the sale and use of food derived from corn line DP202216, genetically modified for enhanced yield and herbicide-tolerance to glufosinate. The sale and use of food derived from corn line DP202216 would be in accordance with the Code.

### **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 A1198 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 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 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. The standing exemption relates to the introduction of a food to the food supply that is voluntary and 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, in alphabetical order, new paragraph '(zc)' into item 2 in the table to subsection S26—3(4) in Schedule 26. Item 2 relates to the commodity 'Corn'.

The new paragraph refers to 'enhanced yield and herbicide-tolerant corn line DP202216'. Corn line DP202216 is a corn line genetically modified for enhanced yield and herbicide-tolerance to glufosinate.

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