

**16 February 2016**  
**[04–16]**

## Approval Report – Application 1112

### Food derived from Herbicide-tolerant Corn Line MZHG0JG

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Syngenta Australia Pty Ltd seeking permission for food derived from corn line MZHG0JG, which is genetically modified to provide tolerance to the herbicides glyphosate and glufosinate ammonium.

On 25 September 2015, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation on 10 February 2016. The Australia and New Zealand Ministerial Forum on Food Regulation<sup>1</sup> (Forum) was notified of FSANZ's decision on 15 February 2016.

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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<sup>1</sup> convening as the Australia and New Zealand Food Regulation Ministerial Council

# Table of Contents

<b>EXECUTIVE SUMMARY .....</b>	<b>1</b>
<b>1 INTRODUCTION.....</b>	<b>3</b>
1.1 THE APPLICANT.....	3
1.2 THE APPLICATION.....	3
1.3 THE CURRENT STANDARD .....	3
1.4 REASONS FOR ACCEPTING APPLICATION.....	3
1.5 PROCEDURE FOR ASSESSMENT .....	3
1.6 DECISION.....	4
<b>2 SUMMARY OF THE FINDINGS .....</b>	<b>4</b>
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS.....	4
2.1.1 <i>General Issues</i> .....	4
2.2 SAFETY ASSESSMENT .....	6
2.3 RISK MANAGEMENT.....	6
2.3.1 <i>Labelling</i> .....	6
2.3.2 <i>Detection methodology</i> .....	7
2.4 RISK COMMUNICATION .....	7
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS.....	7
2.5.1 <i>Section 29</i> .....	7
2.5.2 <i>Subsection 18(1)</i> .....	9
<b>REFERENCES.....</b>	<b>10</b>
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE REVISED <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> (TO COMMENCE ON 1 MARCH 2016) .....	12
ATTACHMENT B – EXPLANATORY STATEMENT.....	14

## Supporting document

The following document, which informed the assessment of this Application, is available on the FSANZ website at <http://www.foodstandards.gov.au/code/applications/Pages/A1112-GM-CornLineMZHGOJG.aspx>

SD1 Safety Assessment Report (at Approval)

## Executive summary

All references to the *Australia New Zealand Food Standards Code* (the Code) in this assessment summary and related SDs are to the revised Code which will take effect on 1 March 2016.

Food Standards Australia New Zealand (FSANZ) received an Application from Syngenta Australia Pty Ltd on 4 May 2015. The Applicant requested a variation to previous Standard 1.5.2 – Food produced using Gene Technology, which in the revised Code represents a variation to Schedule 26. The variation sought is to permit the sale and use of food derived from a genetically modified (GM) corn line that is tolerant to the herbicides glyphosate and glufosinate ammonium.

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in s 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 herbicide-tolerant corn line MZHG0JG (also referred to as MZHG0JG) is provided in Supporting Document 1. 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 MZHG0JG is considered to be as safe for human consumption as food derived from conventional corn cultivars.

The FSANZ Board has approved the draft variation to Schedule 26 to include food derived from herbicide-tolerant corn line MZHG0JG.

# 1 Introduction

## 1.1 The Applicant

Syngenta Australia Pty Ltd is a technology provider to the agricultural sector and food industries.

## 1.2 The Application

Application A1112 was submitted by Syngenta Australia Pty Ltd on 4 May 2015. It sought approval for food derived from herbicide-tolerant corn line MZHG0JG with OECD Unique Identifier SYN-000JG-2 (also referred to as MZHG0JG).

MZHG0JG has been modified to be tolerant to the herbicides glyphosate and glufosinate ammonium.

Tolerance to glyphosate is achieved through expression of the enzyme 5-enolpyruvyl-3-shikimatephosphate synthase (EPSPS) encoded by a modified *epsps* gene (*mepsps*) derived from corn (*Zea mays*). Tolerance to glufosinate is achieved through expression of the enzyme phosphinothricin acetyltransferase (PAT) encoded by the *pat* gene derived from the common soil bacterium *Streptomyces viridochromogenes*. The safety of both proteins has previously been assessed by FSANZ.

## 1.3 The current Standard

FSANZ completed a review of the Code in 2015 and the revised Code will commence on 1 March 2016. Previous Standard 1.5.2 which set out permissions and conditions for the sale and use of food produced using gene technology (a GM food), is replicated in the revised Code with the relevant standard including Schedule 26.

Pre-market approval is necessary before a GM food may enter the Australian and New Zealand food supply. Approval of such foods is contingent on completion of a comprehensive pre-market safety assessment. Foods that have been assessed and approved are listed in Schedule 26.

Standard 1.5.2 in the revised Code contains specific labelling provisions for approved GM foods. As a general rule, GM 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 or if the food is listed in subsections S26-3(2) and (3) of Schedule 26.

## 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 to the Code comes into effect on gazettal. The approved draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

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 Legislative Instruments.

## 2 Summary of the findings

### 2.1 Summary of issues raised in submissions

#### 2.1.1 General Issues

A total of six submissions were received of which two were opposed to the proposed draft variation to Schedule 26. Responses to two general issues raised or implied in the two opposed submissions, are provided in Table 1.

**Table 1: Summary of general issues raised in submissions**

Issue	Raised by	FSANZ response
<p><b>General concern with the use, and possible ingestion, of herbicides on food crops</b></p>	<ul style="list-style-type: none"> <li>• Hugh Halliday</li> <li>• Physicians &amp; Scientists for Global Responsibility (PSGR)</li> </ul>	<p>The use of agricultural and veterinary chemicals (including the adjuvants associated with the raw chemicals) is subject to strict government regulation in most trading countries. In Australia and New Zealand, residues of agricultural and veterinary chemicals are prohibited in food (both GM and non-GM) unless they comply with specific limits referred to as Maximum Residue Limits (MRLs). In New Zealand, they must comply with New Zealand's MRLs Standards which are established by the New Zealand Ministry for Primary Industries. FSANZ and the Australian Pesticides and Veterinary Medicines Authority (APVMA) have shared responsibilities in relation to MRLs for food in Australia. The setting of MRLs ensures that residues of agricultural and veterinary chemicals are kept as low as possible and consistent with the approved use of chemical products to control pests and diseases of plants and animals.</p> <p>In undertaking a risk-based assessment to support an MRL, the key issue is whether, in the context of the Australian/New Zealand diet, the consumption of chemical residues in a food remains below the health-based guidance values.</p> <p>For further details about MRLs see the FSANZ website at: <a href="http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets/chemicalsinfoodmaxim5429.cfm">http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets/chemicalsinfoodmaxim5429.cfm</a> for New Zealand: <a href="http://www.foodsafety.govt.nz/Industry/sectors/plant-products/pesticide-mrl/index.htm">http://www.foodsafety.govt.nz/Industry/sectors/plant-products/pesticide-mrl/index.htm</a></p>
<p><b>Specific concern with the use of glyphosate and glufosinate</b></p>	<ul style="list-style-type: none"> <li>• Hugh Halliday</li> <li>• PSGR</li> </ul>	<p>The following points about <b>glyphosate</b> are relevant:</p> <ul style="list-style-type: none"> <li>• The MRL pertaining to glyphosate is given in Standard 1.4.2 (<a href="http://www.comlaw.gov.au/Details/F2014C01358/Html/Volume_2">http://www.comlaw.gov.au/Details/F2014C01358/Html/Volume_2</a>) and the Applicant has indicated that no change to this MRL is being sought as a result of the intended herbicide use on MZHG0JG.</li> <li>• Glyphosate is a non-selective systemic herbicide with uses on both conventional and GM crops as well as in forestry, industrial weed control, lawn, garden, and aquatic</li> </ul>

Issue	Raised by	FSANZ response
		<p>environments (Henderson et al. 2010).</p> <ul style="list-style-type: none"> <li>• Glyphosate MRLs for a variety of plant-derived food commodities have been adopted by Codex (<a href="http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp">http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp</a>), NZ (<a href="http://www.foodsafety.govt.nz/elibrary/industry/nz-mrl-agricultural-compounds-food-standards-07-2014.pdf">http://www.foodsafety.govt.nz/elibrary/industry/nz-mrl-agricultural-compounds-food-standards-07-2014.pdf</a>) and Australia (<a href="http://www.comlaw.gov.au/Details/F2013C00638">http://www.comlaw.gov.au/Details/F2013C00638</a>).</li> <li>• The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) concluded (FAO 2005) that “the long-term intake of residues of glyphosate... from uses that have been considered by the JMPR is unlikely to present a public health concern”.</li> <li>• A recent monograph<sup>2</sup> released by the WHO International Agency for Research on Cancer (IARC) classified glyphosate as a Group 2A carcinogen (probably carcinogenic to humans). The conclusion is in stark contrast to the ‘non-carcinogenic’ classification given to the herbicide by a number of national and international expert committees. FSANZ has liaised closely with pesticide regulators about their evaluation of the monograph (e.g. the APVMA – who have placed preliminary information on their website at <a href="http://apvma.gov.au/node/13891">http://apvma.gov.au/node/13891</a> including a link to the recent re-assessment of glyphosate by the European Food Safety Authority which did not support the classification of glyphosate as a carcinogen. <a href="http://www.efsa.europa.eu/en/efsajournal/pub/4302">http://www.efsa.europa.eu/en/efsajournal/pub/4302</a>). In light of new studies that have become available, a joint expert Taskforce comprising scientists from the WHO, national governments and universities recommended that the JMPR undertake a full re-evaluation of three herbicides, including glyphosate. This re-evaluation will consider all adverse human health effects, including carcinogenicity. This re-evaluation will be completed by May 2016 when an extraordinary meeting of the JMPR will be convened in Geneva, Switzerland, at WHO headquarters.</li> </ul> <p>The following points about <b>glufosinate</b> are relevant:</p> <ul style="list-style-type: none"> <li>• Glufosinate is a non-selective contact herbicide with uses on a wide range of both conventional and GM crops (JMPR 2013).</li> <li>• The MRL pertaining to glufosinate is given in Standard 1.4.2 of the Code (<a href="http://www.comlaw.gov.au/Details/F2014C01358/Html/Volume_2">http://www.comlaw.gov.au/Details/F2014C01358/Html/Volume_2</a>) and the Applicant has indicated that no change to this MRL is being sought as a result of the intended herbicide use on MZHG0JG..</li> <li>• Glufosinate MRLs for a variety of plant-derived food commodities have been established by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). These MRLs have been adopted by Codex to facilitate international trade in food commodities (<a href="http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp">http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp</a>).</li> <li>• JMPR (2013) concluded that “the long-term intake of residues of glufosinate from uses that have been considered by the JMPR [including a consideration of residues on GM glufosinate-tolerant crops] is unlikely to present a public health concern”.</li> </ul>

<sup>2</sup> IARC (2015). Some organophosphate insecticides and herbicides: Diazinon, glyphosate, malathion, parathion, and tetrachlorvinphos. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 112 available at <http://monographs.iarc.fr/ENG/Monographs/vol112/index.php>.

## **2.2 Safety assessment**

The safety assessment of MZHG0JG is provided in the supporting document (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.

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 MZHG0JG is considered to be as safe for human consumption as food derived from conventional corn cultivars.

The assessment of MZHG0JG 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.

In addition, minor typographical errors in the SD1 released with the Call for Submissions have been corrected.

## **2.3 Risk management**

### **2.3.1 Labelling**

Standard 1.5.2 generally requires food produced using gene technology to be labelled as 'genetically modified' if it contains novel DNA or novel protein. That is, DNA or protein that is different to that found in the counterpart part produced without gene technology.

Some products derived from line MZHG0JG would be unlikely to require labelling as "genetically modified". MZHG0JG is a dent corn and therefore is not a popcorn or sweet corn line, but it is possible that it could be used as a parent in the development of sweet corn lines. The grain from dent corns is mostly processed into refined products such as corn syrup and corn starch which, because of processing, are unlikely to contain any novel protein or novel DNA. Similarly, in the production process for refined corn oil, novel protein and novel DNA are not likely to be present.

MZHG0JG products such as meal (used in bread and polenta) and grits (used in cereals) would be likely to contain novel protein or novel DNA, and if so, would require labelling. Sweet corn kernels containing the SYN-000JG-2 event are also likely to require labelling.

### **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>3</sup> to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food derived from 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 A1112 and hence satisfies the requirement for detection methodology in the version of the *FSANZ Application Handbook* current at the time the application was received (FSANZ 2013).

## **2.4 Risk communication**

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 called 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 25 September and 6 November 2015.

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.

A total of six submissions were received, of which two objected to the proposed variation. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application.

All comments are valued and contribute to the rigour of the safety assessment. Every submission on this application was considered by the FSANZ Board.

Documents relating to Application A1112, including submissions received, are available on the FSANZ website.

## **2.5 FSANZ Act assessment requirements**

### **2.5.1 Section 29**

#### **2.5.1.1 Cost benefit analysis**

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 additional genetically modified foods (reference 12065). The exemption was provided as applications relating to genetically modified food are considered as minor, machinery and deregulatory in nature.

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<sup>3</sup> Now known as the Implementation Subcommittee for Food Regulation

Notwithstanding the above exemption, FSANZ conducted a cost benefit analysis. That analysis found the direct and indirect benefits that would arise from a food regulatory measure, varied as a result of Application A1112, outweigh the costs to the community, Government or industry.

A consideration of the cost/benefit of approving the draft variation is not intended to be an exhaustive, quantitative dollar analysis of the options and, in fact, most of the impacts that are considered cannot be assigned a dollar value. Rather, the analysis seeks to highlight the qualitative impacts of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

The cost/benefit analysis is based on MZHG0JG being approved for growing in other countries since the Applicant has stated that approval for cultivation in Australia or New Zealand is not currently being sought. Cultivation in Australia or New Zealand would require separate regulatory approval (see section 2.5.1.4 below).

*Consumers:* Food from MZHG0JG has been assessed as being as safe as food from conventional cultivars of corn.

Broader availability of imported corn products since, if MZHG0JG is approved for commercial growing in other countries, there would be no restriction on imported foods containing this line.

For those corn line MZHG0JG products containing novel DNA or novel protein, appropriate labelling would allow consumers wishing to avoid these products to do so.

If MZHG0JG is approved for commercial growing in overseas countries, it could be used in the manufacture of products using co-mingled corn seed. This means that there would be no cost involved in having to exclude MZHG0JG from co-mingling and hence that there would be no consequential need to increase the prices of imported foods that are manufactured using co-mingled corn seed.

*Government:* Approval would avoid any conflict with WTO responsibilities. As mentioned above, food from MZHG0JG has been assessed to be as safe as food from conventional cultivars of corn.

This option would be cost neutral in terms of compliance costs, as monitoring is required irrespective of whether or not a GM food is approved.

In the case of approved GM foods, monitoring is required to ensure compliance with the labelling requirements, and in the case of GM foods that have not been approved, monitoring is required to ensure they are not illegally entering the food supply.

*Industry:* Foods derived from MZHG0JG would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of seed of MZHG0JG, as for any GM crop, will be driven by industry, based on market preferences. Implicit in this will be a due regard to the costs of maintaining various levels of purity.

Retailers may be able to offer a broader range of corn products or imported foods manufactured using corn derivatives.

There may be additional costs to the food industry as food ingredients derived from MZHG0JG would require the 'genetically modified' labelling statement if they contain novel DNA or novel protein.

As food from MZHG0JG has been found to be as safe as food from conventional cultivars of corn, not preparing a draft variation would offer little benefit to consumers, as approval of MZHG0JG by other countries could limit the availability of imported corn products in the Australian and New Zealand markets.

Based on the conclusions of the safety assessments, the potential benefits of approving the variation outweighed the potential 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 a food regulatory measure developed or varied as a result of Application A1112.

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

Schedule 26 applies in New Zealand.

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

The Applicant is seeking regulatory approval for MZHG0JG corn cultivation in a number of other countries. It is the Applicant's intention that lines containing event SYN-000JG-2 be commercially cultivated predominantly in North America. There is currently no intention to apply for approval to cultivate lines containing this event in either Australia or New Zealand. Cultivation in Australia or New Zealand would require independent assessment and approval by the Office of the Gene Technology Regulator in Australia and by the Environmental Protection Authority in New Zealand as the case may be.

### **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 MZHG0JG has been assessed according to the safety assessment guidelines prepared by FSANZ (2007). 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 MZHG0JG is considered as safe and wholesome as food derived from other commercial corn cultivars.

#### **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 to enable informed consumer choice, food derived from MZHG0JG would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see discussion in section 2.3.1).

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

The requirement for detection methodology (see section 2.3.2) is designed to 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 2004). Based on these principles, the risk analysis undertaken for food derived from MZHG0JG used the best scientific evidence available. The Applicant submitted to FSANZ a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the Applicants, 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 the production of foods. MZHG0JG is a new food crop designed to expedite future breeding efforts and provide growers with an alternative weed management strategy.

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

Not applicable.

- **any written policy guidelines formulated by the Ministerial Council<sup>4</sup>**

No specific policy guidelines have been developed since Standard 1.5.2 commenced.

## **References**

Codex (2004) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome.  
[http://www.codexalimentarius.net/web/standard\\_list.do?lang=en](http://www.codexalimentarius.net/web/standard_list.do?lang=en)

FAO (2005) Glyphosate. Pesticide residues in food., Food and Agriculture Organization of the United Nations, New York. <http://www.fao.org/docrep/009/a0209e/a0209e0d.htm>

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<sup>4</sup> Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

FSANZ (2007) Safety assessment of genetically modified foods - guidance document. Document prepared by Food Standards Australia New Zealand.  
<http://www.foodstandards.gov.au/publications/Pages/Safety-Assessment-of-Genetically-Modified-Foods-Guidance-Document.aspx>

FSANZ (2013) Application handbook. Prepared by Food Standards Australia New Zealand.  
<http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

Henderson AM, Gervais JA, Luukinen B, Buhl K, Stone D (2010) Glyphosate technical fact sheet., National Pesticide Information Center, Oregon State University Extension Services.  
<http://npic.orst.edu/factsheets/glyphotech.html>

JMPR (2013) Pesticide residues in food 2012. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues - Rome, Italy, 11-20 September 2012. 215. World Health Organization. Food & Agriculture Organization of the United Nations, Rome.  
[http://www.fao.org/fileadmin/templates/agphome/documents/Pests\\_Pesticides/JMPR/Report12/Glu\\_fosinate.pdf](http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report12/Glu_fosinate.pdf)

## **Attachments**

- A. Approved draft variation to the revised *Australia New Zealand Food Standards Code* (to commence on 1 March 2016)
- B. Explanatory Statement

## **Attachment A – Approved draft variation to the revised *Australia New Zealand Food Standards Code* (to commence on 1 March 2016)**



### **Food Standards (Application A1112 – Food derived from Herbicide-tolerant Corn Line MZHG0JG) 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 Standards Management Officer]

Standards Management Officer  
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 the above notice.

**1 Name**

This instrument is the *Food Standards (Application A1112 – Food derived from Herbicide-tolerant Corn Line MZHG0JG) Variation*.

**2 Variation to a standard in the *Australia New Zealand Food Standards Code***

The variation is to a Schedule 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

(x) herbicide-tolerant corn line MZHG0JG

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## **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 A1112 which seeks permission for the sale and use of food derived from herbicide-tolerant corn line MZHG0JG (MZHG0JG). The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to Schedule 26.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation<sup>5</sup>, 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 *Legislative Instruments Act 2003*.

### **2. Purpose**

The variation inserts a reference to herbicide-tolerant corn line MZHG0JG into Schedule 26 of the Code in order to permit the sale, or use in food, of food derived from that corn line.

### **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 A1112 included one round of public consultation following an assessment and the preparation of a draft variation.

A Regulation Impact Statement was not required because the sale of food derived from MZHG0JG, 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.

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<sup>5</sup> convening as the Australia and New Zealand Food Regulation Ministerial Council

## **6. Variation**

Item [1] inserts paragraph (x) into item 2 in the table to subsection S26—3(4) of Schedule 26. The new item refers to herbicide-tolerant corn line MZHG0JG. 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.