20 May 2016
[12–16]

Approval Report – Application A1116

Food derived from Herbicide-tolerant and Insect-protected Corn Line MZIR098

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Syngenta Australia Pty Ltd seeking permission for food derived from corn line MZIR098, which is genetically modified to provide tolerance to the herbicide glufosinate ammonium and be protected against coleopteran pests, particularly western corn rootworm.

On 18 January 2016, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received eight submissions.

FSANZ approved the draft variation on 4 May 2016. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 17 May 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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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/A1116-GMcornMZIR098.aspx

SD1 Safety Assessment Report (at Approval)

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Syngenta Australia Pty Ltd on 10 July 2015. The Applicant requested a variation to the *Australia New Zealand Food Standards Code* (the Code) to permit the sale and use of food derived from a genetically modified (GM) corn line that is tolerant to the herbicide glufosinate ammonium and protected against key coleopteran pests.

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 and insect-protected corn line MZIR098 (also referred to as MZIR098) 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 MZIR098 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 MZIR098.

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 A1116 was submitted by Syngenta Australia Pty Ltd on 10 July 2015. It seeks approval for food derived from herbicide-tolerant and insect-protected corn line MZIR098 with OECD Unique Identifier SYN-00098-3 (also referred to as MZIR098).

MZIR098 has been modified to be tolerant to the herbicide glufosinate ammonium (glufosinate) and protected against key corn coleopteran pests.

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.*

Protection against coleopteran insect pests is conferred by the expression in the plant of a modified Cry3Aa2 protein designated mCry3Aa2 and eCry3.1Ab (a chimeric gene made up of sequences from two different *cry* genes).

1.3 The current standards

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 contains specific labelling provisions for approved GM foods. 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 Legislation.

2 Summary of the findings

2.1 Summary of issues raised in submissions

2.1.1 General Issues

A total of eight submissions were received of which five were opposed to the proposed draft variation to Schedule 26. Of the submissions received, some raised issues that are outside the scope of FSANZ's regulatory area e.g. opinions about biotechnology developers; opinions about other regulatory agencies, environmental issues to do with pesticides. Responses to ten general and relevant issues raised or implied in the five opposed submissions, are provided in Table 1.

Table 1: Summary of general issues raised in submissions

Issue	Raised by	FSANZ response
Concerns with the safety of GM food e.g. increased levels of formaldehyde	• Foodwatch WA • GM Free Australia	The approach used by FSANZ to assess the safety of GM food is based on core principles developed almost 20 years ago and published as guidelines by the Codex Alimentarius Commission (Codex, 2003; Codex, 2004). Over time, the assessment protocol has been the subject of scientific scrutiny and has proved to be a robust approach for whole food safety assessments. It is widely adopted and implemented around the world. While philosophical opposition to the technology remains, consumers can be confident that GM foods assessed under the protocol and approved for food use are as safe as their conventional counterparts. The example cited by Foodwatch WA is a paper by Ayyadurai & Deonikar (2015)[1]. The paper describes a computer simulation (*in silico*) model which predicts significant accumulation of formaldehyde and concomitant depletion of glutathione in Roundup Ready soybeans due to the genetic modification. This study has been recently reviewed by the European Food Safety Authority (EFSA 2015) and other investigators and they have independently concluded that the authors' conclusions cannot be supported because: • The authors looked specifically at glyphosate-tolerant soybean but in their conclusions group all GM crops together as a single entity despite the fact that every GM line from every crop species is quite genetically distinct. • No actual measurement of formaldehyde in the soybean line was undertaken. • Since there has never been a report of increased levels of formaldehyde in glyphosate-tolerant soybean, this indicates that the model used by the authors was not validated. FSANZ has also reviewed the study and concurs with the conclusions of EFSA.

[1] Ayyadurai, V.A.S.; Deonikar, P. (2015). Do GMOs accumulate formaldehyde and disrupt molecular systems equilibria? Systems biology may provide answers. Agricultural Sciences 6: 630 – 662.

Issue	Raised by	FSANZ response
Concerns that MZIR098 has not been assessed as a separate line	• GM Free Australia	The submitter claims that line MZIR098 was developed by crossing previously approved GM corn lines and therefore has not undergone a specific safety assessment. This is not the case – MZIR098 was developed by genetic transformation of the non-GM corn line NP2222 and the specific assessment of MZIR098 is provided in the SD1.
The safety of ingesting transgenes **Horizontal gene transfer**	• Physicians & Scientists for Global Responsibility (PSGR)	DNA is a natural component of the human diet, being present to varying degrees in foods derived from plants and animals, especially those that have undergone minimal processing. There is no difference in terms of risk between recombinant DNA and the DNA already present in our diet. These issues has been considered in detail by FSANZ and a summary is available on the FSANZ website - http://www.foodstandards.gov.au/consumer/gmfood/recombinantdna/Pages/default.aspx
Lack of independent research to support safety conclusions	• PSGR • Foodwatch WA • GE Free Australia	FSANZ requires the developer of any new GM food to demonstrate its safety. The scientific data required to support an application are specified in the FSANZ *Application Handbook* and must be generated according to quality assurance guidelines that are based on internationally accepted protocols and be able to withstand external scrutiny. FSANZ independently assesses the data provided by the developer to reach a conclusion about the safety of the food. FSANZ complements data generated by the developer with information from the scientific literature, other applications, other government agencies and the public. FSANZ has addressed this issue on the website at http://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx
General concern with the use, and possible ingestion, of herbicides on food crops	• Sue Zeckendorf • PSGR • Foodwatch WA	The use of agricultural and veterinary chemicals (including any product specific excipients) 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. MRLs ensure 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. In undertaking a risk-based assessment to support an MRL, an important issue is whether, in the context of the Australian/New Zealand diet, the consumption of chemical residues in a food remains below the appropriate health-based guidance value (ie. Acceptable Daily Intake = ADI or Acute Reference Dose = ARfD). For further details about MRLs see the FSANZ website at: http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets/chemicalsinfoodmaxim5429.cfm. for New Zealand: http://www.foodsafety.govt.nz/Industry/sectors/plant-products/pesticide-mrl/index.htm

Issue	Raised by	FSANZ response
Specific concern with the use of glufosinate	• PSGR	The following points about glufosinate are relevant: • Glufosinate is a non-selective contact herbicide with uses on a wide range of both conventional and GM crops (JMPR 2013). • Glufosinate MRLs for a range of commodities are shown in Schedule 20 of the Code (https://www.legislation.gov.au/Series/F2015L00468) • The Applicant has indicated that no change to this MRL is being sought as a result of the intended herbicide use on MZIR098. • 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 (http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp). • 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".
Concern with safety of ingested *Bt* proteins	• GM Free Australia	There has been widespread consideration about the safety of GM food crops modified to contain Cry genes (see e.g. Mendelsohn et al. 2003; Hammond and Koch 2012; Koch et al. 2015) and the conclusion reached through assessment of the experimental data available and of an 18-year history of safe consumption of food and feed derived from *Bt* crops is that ingestion of food from *Bt* crops does not pose a safety concern. As shown by data presented in the SD1 (Table 4) for MZIR098, levels of the two Cry proteins in the edible part (i.e. grain) of MZIR098 are low. The proteins are readily broken down during cooking or the processing of corn into food fractions (e.g. heating, high pressure extrusion, mechanical shearing, changes in pH and use of reducing agents). Any intact proteins that may remain in a food are then subjected to digestion which further denatures them. Products derived from *B. thuringiensis* have been sprayed on crop plants for 50 years and it is estimated that dietary exposure to *B*t proteins from ingestion of microbial spray formulations is higher than that from consumption of GM crops (Koch et al, 2015). The effect of these products on human health and the environment was the subject of a critical review by the WHO International Programme on Chemical Safety (WHO 1999). The review concluded that '*B. thuringiensis* products are unlikely to pose any hazard to humans or other vertebrates or the great majority of non-target invertebrates' Products containing *Bt* are approved for use on crops in Australia and New Zealand and in both countries there is an exemption from MRLs when *Bt* is used as an insecticide.

Issue	Raised by	FSANZ response
Lack of consideration of long term feeding studies in the safety assessment	• PSGR • GM Free Australia	There is general consensus among food regulators that the key focus in determining the safety of a GM food is the comparative compositional analysis. This concept was first considered and adopted in 1993 (OECD 1993) and there has not been any change to this approach (Herman et al. 2009). The compositional analysis of grain from MZIR098 showed that it is compositionally equivalent to grain from conventional corn varieties. In 2007, FSANZ convened a workshop to formally examine the usefulness of animal feeding studies to support the safety assessment of GM foods (http://www.foodstandards.gov.au/consumer/gmfood/Pages/roleofanimalfeedings3717.aspx). The conclusion was that such studies do not contribute meaningful information on the long-term safety of a GM food, with the possible exception of a food in which the modification introduced a desired nutritional change. Therefore, for most GM foods, including those derived from MZIR098, feeding trials of any length are unlikely to contribute any further useful information to the safety assessment and are not warranted. There are also concerns about the unethical use of animals for feeding studies in the absence of any clearly identified compositional differences (Rigaud 2008; Bartholomaeus et al. 2013).
Livestock fed GM feed have suffered adverse consequences	• PSGR	The submitter cites as one example the anecdotal case of the German farmer Gottfried Glöckner who, in 2001, included grain/silage from corn line Bt176 in feed for his dairy cows. A number of abnormal deaths followed and this outcome was investigated by the Robert Koch Institute. While no specific cause for the deaths was ever elucidated, there was no convincing evidence of a link with consumption of Bt 176 feed. Several subsequent scientifically conducted studies in which Bt176 feed was given to a variety of livestock did not show any evidence of harm (see e.g. Flachowsky et al. 2007) A recent review (Van Eenennaam and Young 2014) looking at the data on 100 billion livestock animals fed GM animal feed over a period of 15 years did not reveal unfavourable or perturbed trends in livestock health and productivity.
FSANZ must give clear direction on labelling	• GM Free Australia	Precise labelling requirements are given in Standard 1.5.2 and Schedule 26 and are legally binding (referenced in Part 1.3 of this Approval Report). In the case of corn line MZIR098, the presence of novel DNA or novel protein in the final food will trigger the mandatory labelling statement. In Part 2.3.1 of this Approval Report, FSANZ has provided likely labelling scenarios for possible products of MZIR098. The wording is deliberately open-ended and in no way is intended to either replace the precise regulation conveyed in the relevant standards or be taken as definitive instruction to food processors.

2.2 Safety assessment

The safety assessment of MZIR098 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 MZIR098 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

The assessment of MZIR098 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 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 food produced without gene technology.

Some products derived from line MZIR098 would be unlikely to require labelling as "genetically modified". MZIR098 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.

MZIR098 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-00098-3 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[2] 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 A1116 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] Now known as the Implementation Subcommittee for Food Regulation

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 18 January and 29 February 2016.

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 eight submissions were received, of which five 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 A1116, 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.

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 A1116, 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 MZIR098 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 MZIR098 has been assessed as being as safe as food from conventional cultivars of corn.

Broader availability of imported corn products since, if MZIR098 is approved for commercial growing in other countries, there would be no restriction on imported foods containing this line.

For those corn line MZIR098 products containing novel DNA or novel protein, appropriate labelling would allow consumers wishing to avoid these products to do so.

If MZIR098 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 MZIR098 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 MZIR098 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 MZIR098 would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of seed of MZIR098, 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 MZIR098 would require the 'genetically modified' labelling statement if they contain novel DNA or novel protein.

As food from MZIR098 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 MZIR098 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 A1116.

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 MZIR098 corn cultivation in a number of other countries. It is the Applicant's intention that lines containing event SYN-00098-3 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 MZIR098 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 MZIR098 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 MZIR098 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 MZIR098 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. MZIR098 is a new food crop designed to expedite future breeding efforts and provide growers with alternative weed and pest management strategies.

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

Not applicable.

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

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

3 References

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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 A1116 – Food derived from Herbicide-tolerant & Insect-protected Corn Line MZIR098) 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 A1116 – Food derived from Herbicide-tolerant & Insect-protected Corn Line MZIR098) 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

(z) herbicide-tolerant and insect-protected corn line MZIR098

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 A1116 which seeks permission for the sale and use of food derived from herbicide-tolerant and insect-protected corn line MZIR098 (MZIR098). 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, 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 sunsetting under the *Legislation Act 2003*.

2. Purpose

The variation inserts a reference to herbicide-tolerant and insect-protected corn line MZIR098 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 A1116 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 MZIR098, if approved, would be voluntary and would be likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] inserts paragraph (z) into item 2 in the table to subsection S26—3(4) of Schedule 26. The new item refers to herbicide-tolerant and insect-protected corn line MZIR098. 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.