2 October 2015
[24–15]

Approval Report – Application 1106

Food derived from Herbicide-tolerant & Insect-protected Corn Line 4114

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Pioneer Hi-Bred Australia Pty Ltd seeking permission for food derived from corn line 4114, which is genetically modified to provide tolerance to the herbicide glufosinate ammonium, and protection against lepidopteran and coleopteran pests of corn.

On 2 June 2015 FSANZ sought submissions on a draft variation to Standard 1.5.2 and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variations on 17 September 2015. The Australia and New Zealand Ministerial Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 1 October 2015.

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

[1] convening as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting documents

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/A1106-Herbicide-tolerantInsect-protectedCornLine4114.aspx

SD1 Safety Assessment Report (at Approval)

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Pioneer Hi-Bred Australia Pty Ltd on 10 December 2014. The Applicant requested a variation to Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code). The variation sought is to permit the sale and use of food derived from a genetically modified (GM) corn, line 4114, that is tolerant to the herbicide glufosinate ammonium and protected against lepidopteran and 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 4114 (also referred to as line 4114) 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 line 4114 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 Standard 1.5.2 in the current Code and Schedule 26 of the revised Code (to commence on 1 March 2016) to include food derived from herbicide-tolerant corn line 4114 in the Schedule.

1 Introduction

1.1 The Applicant

Pioneer Hi-Bred Australia Pty Ltd is a subsidiary of DuPont Pioneer, a multinational seed and technology provider to the agricultural sector and food industries.

1.2 The Application

Application A1106 was submitted by Pioneer Hi-Bred Australia Pty Ltd on 10 December 2014. It sought approval for food derived from herbicide-tolerant and insect-protected corn line 4114 with OECD Unique identifier DP-004114-3 (also referred to as line 4114) under Standard 1.5.2 – Food produced using Gene Technology.

Line 4114 has been modified to be tolerant to the herbicide glufosinate ammonium and protected against lepidopteran and coleopteran pests of corn.

Tolerance to glufosinate ammonium is achieved through expression of the enzyme phosphinothricin acetyltransferase (PAT) encoded by the *pat* gene derived from the common soil bacterium *Streptomyces viridochromogenes.* This protein has been considered in 19 previous FSANZ approvals and globally is represented in six major crop species and over 30 approved GM single plant events.

Protection against lepidopteran insect pests is conferred by the *cry1F* gene, which is a synthetic version of a gene from *Bacillus thuringiensis* var. *aizawai,* and encodes a truncated version of an insecticidal protein, Cry1F. Protection against coleopteran insect pests is conferred by two genes, *cry34Ab1* and *cry35Ab1* both from *B. thuringiensis* strain PS149B1 and encoding the insecticidal proteins Cry34Ab1 and Cry35Ab1. These proteins have both been considered previously by FSANZ.

Line 4114 is a molecular stack that, in terms of traits, is the equivalent of a breeding stack obtained by crossing two corn lines, 1507 x 59122. Food from both of these lines has been separately approved by FSANZ and hence, food from the breeding stack is also approved to enter the Australian and New Zealand food supplies. Food from line 4114 requires a separate approval since it represents a unique molecular event even though the expressed traits are the same as those already 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. Current Standard 1.5.2 which sets out permission 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 being 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 the Schedule to Standard 1.5.2 in the current Code and Schedule 26 of the revised Code.

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 and/or novel protein (as defined in Standard 1.5.2) is present in the final food, or the food has altered characteristics.

In the latter case, the Standard also allows for specific additional labelling about the nature of the altered characteristics.

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 current Code comes into effect on gazettal. The approved draft variation and related explanatory statement are at Attachment A.

The draft variation to the revised Code, and related explanatory statement, are at Attachment B. The variation is intended to take effect on 1 March 2016.

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 four submissions were received. Responses to five general issues raised or implied in 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 and the FSANZ safety assessment process	• Susie Lees • Physicians & Scientists for Global Responsibility (PSGR)	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.

Issue	Raised by	FSANZ response
		In 2008, an external review of the FSANZ GM food safety assessment procedure was undertaken. The findings of the review are available at http://www.foodstandards.gov.au/consumer/gmfood/pages/reviewofgeneticallym4394.aspx Studies cited as evidence of safety concerns with certain GM foods have been examined by FSANZ and other scientific experts around the world. The studies have been subject to significant scientific criticism and generally are not supported. Responses to several recent publications are available on the FSANZ website (http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx).
Lack of consideration of long term feeding studies in the safety assessment	• Susie Lees • PSGR	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 in 1993 (OECD 1993) and there has not been any change to this thinking (Herman et al. 2009). The compositional analysis of grain from line 4114 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 line 4114, 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).
The safety of ingesting transgenes **Horizontal gene transfer**	• PSGR	DNA is a natural component of the human diet, being present to varying degrees in plant- and animal- derived foods, 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
Concern with the use of herbicides in general and glufosinate in particular	• Susie Lees • PSGR	The use of agricultural and veterinary 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 MRL 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.

Issue	Raised by	FSANZ response
		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. 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. Herbicide MRLs themselves are not food safety limits. They specify the amount of permitted residue remaining in a harvested crop after the minimum amount of herbicide has been applied to control weed growth. 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 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). • The MRL pertaining to glufosinate is given in Standard 1.4.2 of the Code (http://www.comlaw.gov.au/Details/F2014C01358/Html/Volume_2) and the Applicant has indicated that no change to this MRL is being sought as a result of the intended herbicide use on line 4114. • 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”.
Bt crops have been linked to health and environmental issues	• Susie Lees • PSGR	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 data available is that *Bt* crops do not pose a safety concern. It is also relevant to note that products derived from *B. thuringiensis* have been sprayed on crop plants for 50 years. 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.

2.1.2 Specific issues raised

The New Zealand Ministry for Primary Industries commented that there appeared to be a slight discrepancy between the apparent molecular weights for plant derived Cry1F and Cry35Ab1 and those of the respective bacterially-derived standard proteins on Western Blots (discussed in Section 4.1.4 of the SD1).

The text in the SD1 has been altered to indicate that proteases are the likely cause of the doublet band observed for the plant derived protein.

2.2 Safety assessment

The safety assessment of line 4114 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.

The assessment of line 4114 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. As explained below, these risks are assessed under Australian and New Zealand environmental laws.

No potential public health and safety concerns have been identified.

Based on the scientific data provided in the present Application, and other available information, food derived from line 4114 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

2.3 Risk management

2.3.1 Labelling

In accordance with Standard 1.5.2 in both the current and revised versions of the Code, food derived from line 4114 would be required to be labelled as 'genetically modified' if it contains novel DNA and/or novel protein; or if it has altered characteristics. Food from line 4114 does not have altered characteristics.

Line 4114 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. Therefore such products derived from line 4114 would be unlikely to require labelling.

Line 4114 products such as meal (used in bread and polenta) and grits (used in cereals) would be likely to contain novel protein and novel DNA, and if so, would require labelling. Sweet corn kernels containing the DP-004114-3 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 has indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA is 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 is publicly available in a patent and hence satisfies the requirement for detection methodology in the FSANZ *Application Handbook* (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 2 June and 14 July 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 four 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 A1106, 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 of 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.

FSANZ undertook a cost benefit analysis (see below). The analysis concluded the direct and indirect benefits that would arise from a food regulatory measure, varied as a result of Application A1106, outweigh the costs to the community, Government or industry.

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

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 points below list the effect that approving the draft would be expected to have on various sectors. It is noted that the cost/benefit analysis is based on line 4114 (and any lines containing the 4114 event) being approved for growing in other countries (see section 2.5.1.4 below).

Consumers: Broader availability of imported corn products. Line 4114 is approved for commercial growing in other countries and therefore there would be no restriction on imported foods containing this line.

For those line 4114 products containing novel DNA or novel protein, appropriate labelling would allow consumers wishing to avoid these products to do so.

Since line 4114 is approved for commercial growing in overseas countries, it can be used in the manufacture of products using co-mingled corn.

This means that there would be no cost involved in having to exclude line 4114 from co-mingling and hence that there would be no consequential need to increase the prices of imported foods that are manufactured using comingled corn products.

Government: Benefit that if line 4114 was detected in food imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Line 4114 is approved for commercial growing in overseas countries and thus approval of line 4114 would ensure no conflict with Australia's and New Zealand's international trade obligations responsibilities.

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. The costs of monitoring are thus expected to be comparable, whether a GM food is approved or not.

Industry: Importers of processed foods containing corn derivatives would benefit as foods derived from line 4114 would be compliant with the Code, allowing broader market access and increased choice in raw materials.

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

Possible cost to food industry as food ingredients derived from line 4114 would be required to be labelled if they contain novel DNA or novel protein.

The segregation of raw agricultural commodities of line 4114, 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.

As food from line 4114 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 line 4114 by other countries could limit the availability of imported corn products in the Australian and New Zealand markets. In addition, this option would result in the requirement for segregation of any products containing line 4114 from those containing approved corn lines which would be likely to increase the costs of imported corn-derived foods.

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 A1106.

2.5.1.3 Any relevant New Zealand standards

Standard 1.5.2 applies in New Zealand.

2.5.1.4 Any other relevant matters

The Applicant has submitted applications for regulatory approval of line 4114 to a number of other countries, as listed in Table 2. All of these have been finalised as indicated.

Table 2: List of countries to whom applications for regulatory approval of line 4114 have been submitted

Country	Agency	Type of approval sought	Status
USA	Department of Agriculture	environment[1]	Authorised 20/06/2013
	Food & Drug Administration	food/feed	Consultation completed 25/03/2013
	Environmental Protection Agency	environment[1]	Authorised 07/06/212
Canada	Food Inspection Agency	environment[1]	Authorised 21/06/2013
	Health Canada	food	Authorised 19/06/2013
Japan	Ministry of Health, Labour and Welfare	food	Authorised 15/01/2015
	Ministry of Agriculture, Forestry & Fisheries	feed	Authorised 30/01/2015
	Ministry of Agriculture, Forestry & Fisheries	environment[1]	Authorised 19/02/2015
Korea	Ministry of Food and Drug Safety	food	Authorised 10/10/2014
	Rural Development Administration	feed	Authorised 04/09/2014
Mexico	Department of Health	food/feed	Authorised 07/01/2014
Taiwan	Ministry of Health & Welfare	food/feed	Authorised 27/06/2014

[1]an authorisation for 'environment' indicates the line can be grown commercially in that country.

It is the Applicant's intention that lines containing event DP-004114-3 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.

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 line 4114 has been assessed according to the safety assessment guidelines prepared by FSANZ (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 line 4114 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 line 4114 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 General Principles for the Risk Analysis of Foods derived from Biotechnology (Codex 2004). Based on these principles, the risk analysis undertaken for line 4114 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. Line 4114 is a new food crop designed to provide growers with alternative pest and weed management strategies.

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

Since line 4114 is approved for commercial growing in other countries, it is appropriate that Australian and New Zealand importers have access to food products derived from the line.

- **any written policy guidelines formulated by the Ministerial Council**[3]

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

3 Transitional arrangements

3.1 Transitional arrangements for Code Revision

FSANZ has completed a review of the Code undertaken under Proposal P1025[4] in order to improve its clarity and legal efficacy. Following approval of the revision and Ministerial consideration, the new Code will commence on 1 March 2016 (following gazettal on 10 April 2015 and registration on the Federal Register of Legislative Instruments). The current Code will also be repealed on this date. The approved variation at Attachment B varies the revised Code on 1 March 2016 to ensure that the revised Code is consistent with the current Code as amended by the variation at Attachment A.

4 References[5]

Bartholomaeus A, Parrott W, Bondy G, Walker K (2013) The use of whole food animal studies in the safety assessment of genetically modified crops: Limitations and recommendations. Critical Reviews in Toxicology 43(S2):1–24

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

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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/Glufosinate.pdf

Koch MS, Ward JM, Levine SL, Baum JA, Vicini JL, Hammond BG (2015) The food and environmental safety of Bt crops. Frontiers in Plant Science 6:283

[3] Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)
[4] http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx
[5] Internet references were current as at 4 August 2015

Mendelsohn M, Kough J, Vaituzis Z, Matthews K (2003) Are Bt crops safe? Nature Biotechnology 21:1003–1009

OECD (1993) Safety evaluation of foods derived by modern biotechnology: Concepts and principles. Organisation for Economic Co-operation and development, Paris

Rigaud N (2008) Biotechnology: ethical and social debates. OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda". http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/40926844.pdf

WHO. Microbial pest control agent Bacillus thuringiensis. (217). 1999. Geneva, World Health Organization. Environmental Health Criteria.

Attachments

A. Approved draft variation to the *Australia New Zealand Food Standards Code* and related Explanatory Statement
B. Approved draft variation to the revised *Australia New Zealand Food Standards Code* and related Explanatory Statement (commencing 1 March 2016)

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

Food Standards (Application A1106 – Food derived from Herbicide-tolerant & Insect-protected Corn Line 4114) 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 Standard commences on the date specified in clause 3 of this 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 clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1106 – Food derived from Herbicide-tolerant and Insect-protected Corn Line 4114) 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] Standard 1.5.2 is varied by inserting in Item numerical order in the Schedule

“

	2.23	Food derived from herbicide-tolerant and insect-protected corn line 4114	

”

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.

FSANZ accepted Application A1106 which seeks permission for the sale and use of food derived from herbicide-tolerant and insect-protected corn line 4114 (line 4114). The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation[6], 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 *Legislative Instruments Act 2003*.

2. Purpose

The variation inserts a reference to herbicide-tolerant and insect-protected corn line 4114 into the Schedule to Standard 1.5.2 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 A1106 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 Application is 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] convening as the Australia and New Zealand Food Regulation Ministerial Council

6. Variation

Item [1] inserts Item 2.23 into the Schedule to Standard 1.5.2. Item 2.23 refers to food derived from herbicide-tolerant and insect-protected corn line 4114.

Attachment B – Approved draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

***Australia New Zealand Food Standards Code* – Transitional Variation 2015 (Application A1106 – Food derived from Herbicide-tolerant & Insect-protected Corn Line 4114)**

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 Standard commences on the date specified in clause 3 of this 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 clause 3 of the variation.

1 Name

This instrument is the *Australia New Zealand Food Standards Code – Transitional Variation 2015 (Application A1106 – Food derived from Herbicide-tolerant and Insect-protected Corn Line 4114)*.

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

The Schedule varies Schedule 26 of the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions – 2014 Revision.

SCHEDULE

[1] The item 'Corn' in the Table to subsection S26—3(4) of Schedule 26 is varied by inserting in the appropriate alphabetical position

"

(w) herbicide-tolerant and insect-protected corn line 4114

"

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.

FSANZ accepted Application A1106 which seeks permission for the sale and use of food derived from herbicide-tolerant and insect-protected corn line 4114 (line 4114). The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation[7], 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 *Legislative Instruments Act 2003*.

2. Purpose

The variation inserts a reference to herbicide-tolerant and insect-protected corn line 4114 into Schedule 26 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 A1106 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 use of food derived from line 4114, 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.

[7] convening as the Australia and New Zealand Food Regulation Ministerial Council

6. Variation

Item [1] varies the item ‘Corn’ in the table to subsection S26—3(4) of Schedule 26 by inserting a reference to herbicide-tolerant and insect-protected corn line 4114. 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.