29 June 2016
[16-16]

Approval Report – Application A1118

Food derived from Herbicide-tolerant Corn Line MON87419

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Monsanto Australia Ltd seeking permission for food derived from corn line MON87419, which is genetically modified to provide tolerance to the herbicides dicamba and glufosinate ammonium.

On 9 February 2016, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received seven submissions.

FSANZ approved the draft variation on 16 June 2016. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 28 June 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/A1118GM-CornLineMON87419.aspx

SD1 Safety Assessment Report

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Ltd on 11 August 2015. The Applicant requested a variation to permit the sale and use of food derived from a genetically modified (GM) corn line that is tolerant to the herbicides dicamba 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 MON87419 is provided in Supporting Document 1. No potential public health and safety concerns have been identified. Based on the data provided in the Application, and other available information, food derived from MON87419 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 MON87419.

1 Introduction

1.1 The Applicant

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

1.2 The Application

Application A1118 was submitted by Monsanto Australia Ltd on 11 August 2015. It sought approval for food derived from herbicide-tolerant corn line MON87419 with OECD Unique Identifier MON-87419-8 (herein referred to as MON87419).

MON87419 has been modified to be tolerant to the herbicides dicamba and glufosinate ammonium.

Tolerance to dicamba is achieved through expression of the enzyme dicamba mono-oxygenase (DMO) encoded by the *dmo* gene derived from a common soil and aquatic bacterium *Stenotrophomonas maltophilia*. 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

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. 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. Foods listed in subsections S26—3(2) and (3) of Schedule 26 must also be labelled with the words 'genetically modified', as well as any other additional labelling required by the Schedule, regardless of the presence of novel DNA or novel protein in the foods. These foods listed in subsections S26—3(2) and (3) have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not produced using gene technology.

1.4 Reasons for accepting the Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the 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.

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 seven submissions were received of which four were opposed to the proposed draft variation to Schedule 26. Responses to the issues raised or implied in the four opposed submissions, are provided in Table 1.

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ response
Opposed to genetic modification of foods but if approved all GM foods should be labelled	• Peter Sutherland, Director Softlaw Community Projects Ltd • Physicians & Scientists for Global Responsibility (PSGR)	Only those GM foods assessed by FSANZ as safe are approved for sale. The labelling of approved GM foods is therefore not for safety reasons. Specific labelling requirements are in Standard 1.5.2 and Schedule 26 (referenced in section 1.3 of this Report). In the case of corn line MON87419, the presence of novel DNA or novel protein in the final food will trigger the mandatory labelling statement. In section 2.3.1 of this Report, FSANZ has provided likely labelling scenarios for possible products of MON87419. Further information on the labelling of GM foods can be found on the FSANZ website at: http://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx
The evidence and impact of the susceptibility of the introduced proteins to digestive enzymes; and any digestive difference in consuming these proteins in the GM corn	• John Fitzpatrick private submitter	The evidence from a number of studies related to the susceptibility of the introduced DMO and PAT proteins to digestive enzymes is reviewed in section 4.1.4 of SD1. These studies contribute to the overwhelming weight of evidence which suggests the introduced proteins are not toxic or allergenic and raise no food safety concerns (see section 4.1.6 in SD1). There is no evidence to suggest the introduced proteins would be digested any differently than most other dietary proteins.

Issue	Raised by	FSANZ response
The safety of ingesting transgenes.	• 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. This issue 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.
General concerns about the use of pesticides and insecticides on GM corn.	• Gerry Douglas, private submitter • PSGR	Corn line MON87419 was primarily developed for agriculture in North America and if the current Application is approved, food derived from this line may enter the Australian and New Zealand food supply as imported food products. Approval for cultivation in Australia or New Zealand has not been sought. Cultivation of the GM corn line would require assessment and approval from agencies such as the OGTR and APVMA in Australia and the EPA in New Zealand. The use of agricultural and veterinary chemicals (including the excipients associated with the active constituent) 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 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. 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. 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 ammonium and dicamba.	• PSGR	The following points about the herbicides are relevant: • Glufosinate is a non-selective contact herbicide (JMPR 2013) and diacamba is a systemic broad-spectrum herbicide (JMPR 2014). Both herbicides can be used on a wide range of both conventional and GM crops. • There is approval in the Code for glufosinate and dicamba MRLs for a range of commodities in Schedule 20 (https://www.legislation.gov.au/Series/F2015L00468) • The Applicant has indicated that no change to the MRL is being sought as a result of the intended use of glufosinate herbicide on MON87419. However, a request will be submitted to establish an import MRL to cover residues of dicamba on corn into Australia. • Glufosinate and dicamba 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 concluded that the long-term intake of residues of glufosinate (2013) or dicamba (2014) from uses that have been considered by the JMPR were unlikely to present a public health concern.
Concern with the safety of all GM food, including the assessment process	• 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 but 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. Compositional analysis and nutritional impact of food derived from the GM corn was considered in sections 5 and 6 of SD1. The conclusion from these sections was that grain from MON87419 can be regarded as equivalent in composition to grain from conventional corn and is expected to have little nutritional impact.

Issue	Raised by	FSANZ response
Lack of animal feeding studies to address concerns about long term toxicity; desire to have GM foods tested in the same way that pharmaceuticals are tested.	• PSGR	As indicated above, the approach used by FSANZ to assess the safety of GM foods is based on robust principles and guidelines that are accepted internationally and have withstood scientific scrutiny. 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 MON87419 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 MON87419, 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).

2.2 Safety assessment

The safety assessment of MON87419 is provided in SD1 and included the following key elements:

- 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 Application, and other available information, food derived from MON87419 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

The assessment of MON87419 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. Cultivation in Australia or New Zealand would require separate regulatory approval (see section 2.5.1.4 below).

2.3 Risk management

2.3.1 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food derived from MON87419 would be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein. Food derived from MON87419 would not be listed in subsections S26—3(2) and (3) of Schedule 26 as FSANZ's assessment is that it would not have an altered characteristic when compared to the existing counterpart food that is not produced using gene technology.

Some products derived from line MON87419 are unlikely to require labelling as 'genetically modified'. MON87419 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.

MON87419 products such as meal (used in bread and polenta) and grits (used in cereals) would likely contain novel protein or novel DNA, and if so, would require labelling. Sweet corn kernels containing the MON-87419 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[1] 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 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 9 February and 22 March 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.

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

A total of seven submissions were received, of which four 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 A1118, 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 A1118, 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 MON87419 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 MON87419 has been assessed as being as safe as food from conventional cultivars of corn.

Broader availability of imported corn products since, if MON87419 is approved for commercial growing in other countries, there would be no restriction on imported foods containing this line.

For those corn line MON87419 products containing novel DNA or novel protein, labelling would allow consumers wishing to avoid these products to do so.

If MON87419 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 MON87419 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 MON87419 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 MON87419 would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of seed of MON87419, 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 MON87419 would require the 'genetically modified' labelling statement if they contain novel DNA or novel protein.

As food from MON87419 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 MON87419 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 A1118.

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 has submitted applications for regulatory approval of MON87419 to a number of other countries, as listed in Table 1.

Table 1: List of countries to whom applications for regulatory approval of MON87419 have been submitted

Country	Agency	Type of approval sought	Status
USA	U.S. Department of Agriculture	environment	Approved 2016
	Food & Drug Administration	food/feed	Approved 2016
Canada	Health Canada	food	Approved 2016
	Canadian Food Inspection Agency (CFIA)	feed/environment	Approved 2016
Japan	Ministry of Health, Labour and Welfare	food	Under assessment
	Ministry of Agriculture, Forestry & Fisheries	feed	Under assessment
	Ministry of Agriculture, Forestry and Fisheries / Ministry of the Environment	environment	Under assessment
Korea	Ministry of Food and Drug Safety	food	Under assessment
	Rural Development Administration	feed	Under assessment
Taiwan	Department of Health	food	Under assessment
Argentina	National Advisory Commission on Agriculture Biotechnology (CONABIA)	environment	Under assessment
	National Health Service and Food Quality (SENASA)	food/feed	Under assessment
China	Ministry of Agriculture	food/feed	Under assessment

The Applicant is seeking regulatory approval for MON87419 corn cultivation in a number of other countries. It is the Applicant's intention that lines containing event MON-87419-8 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 MON87419 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 MON87419 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 MON87419 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 MON87419 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. MON87419 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 Forum on Food Regulation**

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

References

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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

Attachments

A. Approved draft variation to the revised *Australia New Zealand Food Standards Code*
B. Explanatory Statement

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

Food Standards (Application A1118 – Food derived from Herbicide-tolerant Corn Line MON87419) 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 A1118 – Food derived from Herbicide-tolerant Corn Line MON87419) 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 Cod*e.

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

(za) herbicide-tolerant corn line MON87419

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 A1118 which seeks permission for the sale and use of food derived from herbicide-tolerant corn line MON87419. 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 corn line MON87419 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 A1118 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 MON87419, 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 (za) into item 2 in the table to subsection S26—3(4) of Schedule 26. The new item refers to herbicide-tolerant corn line MON87419. 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.