

**16 December 2014**  
**[26–14]**

## **Call for submissions – Application A1097**

### **Food derived from Herbicide-tolerant and Insect-protected Corn Line MON87411**

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FSANZ has assessed an Application made by Monsanto Australia Ltd seeking permission for food derived from corn line MON87411, which is genetically modified to provide tolerance to the herbicide glyphosate and protection against corn rootworm, in particular western corn rootworm, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 10 February 2015**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Hard copy submissions may be sent to one of the following addresses:

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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/A1097GMCornLineMON87411.aspx>

SD1 Safety Assessment Report: Application A1097 – Food derived from Herbicide-tolerant and Insect-protected Corn Line MON87411

## Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Ltd on 15 July 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, MON87411, that is tolerant to the herbicide glyphosate and protected against western corn rootworm.

This Application is being assessed under the General Procedure.

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 MON87411 (also referred to as MON87411) 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 MON87411 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

FSANZ has prepared a draft variation to Standard 1.5.2 to include food derived from herbicide-tolerant and insect-protected corn line MON87411

# 1 Introduction

## 1.1 The Applicant

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

## 1.2 The Application

Application A1097 was submitted by Monsanto Australia Ltd on 15 July 2014. It sought approval for food derived from herbicide-tolerant and insect-protected corn line MON87411 (also referred to as MON87411) under Standard 1.5.2 – Food produced using Gene Technology.

MON87411 has been modified such that it is both tolerant to the herbicide glyphosate and protected against corn rootworm, particularly western corn rootworm.

Tolerance to glyphosate is achieved through expression of the enzyme 5-enolpyruvyl-3-shikimatephosphate synthase (CP4 EPSPS) encoded by the *cp4epsps* gene derived from the common soil bacterium *Agrobacterium* sp. strain CP4. The CP4 EPSPS protein in corn line MON87411 is identical to the CP4 EPSPS protein present in 14 other lines that have been developed by Monsanto and approved by FSANZ.

Protection against corn rootworm occurs via two genetic modifications:

- The expression of a *cry3Bb1* gene that produces a modified *Bacillus thuringiensis* (subsp. *kumamotoensis*) Cry3Bb1 protein to protect against larval feeding. The safety of the Cry3Bb1 protein has been previously assessed by FSANZ in two other approvals involving corn rootworm-protection.
- The expression of a suppression cassette containing an inverted repeat sequence from the western corn rootworm (*Diabrotica virgifera virgifera*) *Snf7* gene. This sequence is expressed in the tissue of corn line MON87411 and results in the formation of a double-stranded RNA (dsRNA) transcript containing a fragment of the *Snf7* gene. When plant tissue is ingested by corn rootworm, the plant-produced dsRNA is recognised by the corn rootworm RNA interference (RNAi) machinery and results in down-regulation of the endogenous *Snf7* gene and subsequent death of the insect.

## 1.3 The current Standard

Standard 1.5.2 sets out the permission and conditions for the sale and use of food produced using gene technology (a GM food).

Pre-market approval is necessary before a GM food may enter the Australian and New Zealand food supply. Approval of such foods under Standard 1.5.2 is contingent on completion of a comprehensive pre-market safety assessment. Foods that have been assessed and approved are listed in the Schedule to the Standard.

Standard 1.5.2 contains specific labelling provisions for approved GM foods. Such foods 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 additional labelling about the nature of the altered characteristics.

## **1.4 Reasons for accepting the Application**

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- 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 is being assessed under the General Procedure.

# **2 Summary of the assessment**

## **2.1 Safety assessment**

The safety assessment of MON87411 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 MON87411 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.

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 MON87411 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

## **2.2 Risk management**

### **2.2.1 Labelling**

GM foods are labelled to help consumers make an informed choice. In accordance with Standard 1.5.2, food derived from MON87411 would be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein; or if it has altered characteristics. MON87411 does not have altered characteristics.

MON87411 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, is 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 MON87411 would be unlikely to require labelling.

MON87411 corn 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 MON87411 event are also likely to require labelling.

### **2.2.2 Detection methodology**

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee<sup>1</sup> to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food derived from gene technology (GM applications).

The EAG 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 was supplied by the Applicant for MON87411 to satisfy the requirement for detection methodology in the FSANZ *Application Handbook* (FSANZ, 2013).

## **2.3 Risk communication**

### **2.3.1 Consultation**

Consultation is a key part of FSANZ's Standards development process.

FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received on this call for submissions.

The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the assessment.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council). If the Board's decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the website.

### **2.3.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

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<sup>1</sup> Now known as the Implementation Subcommittee for Food Regulation

There are not any relevant international standards, and amending the Code to permit food derived from MON87411 is unlikely to have a significant effect on international trade as it would permit food derived from MON87411 to be imported into Australia and New Zealand and sold, where currently sale is prohibited. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## **2.4 FSANZ Act assessment requirements**

### **2.4.1 Section 29**

#### **2.4.1.1 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). This standing exemption was provided as such changes are considered as minor, machinery and deregulatory in nature. The exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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 developed or varied as a result of the Application outweigh the costs to the community, Government or industry that would arise from the development or variation of that measure.

FSANZ's consideration of the cost/benefit of the regulatory options is not intended to be an exhaustive, quantitative financial analysis of the options as 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 the assumption that MON87411 will be 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.

#### *Option 1 – Prepare a draft variation to Standard 1.5.2*

**Consumers:** Broader availability of imported corn products as, if MON87411 is approved for commercial growing in other countries, there would be no restriction on imported foods containing this line.

For those corn products derived from MON87411 which contain novel DNA and/or novel protein, appropriate labelling would allow consumers wishing to avoid these products to do so.

If MON87411 is approved for commercial growing in overseas countries it can 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 MON87411 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:** If MON87411 was detected in food imports, approval would ensure compliance with the Code and prevent any trade disruption on regulatory grounds.

Approval would result in no conflict with WTO responsibilities if the line is approved for commercial growing in other countries.

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 MON87411 would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of seed of MON87411, 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 some food ingredients derived from MON87411 would be required to be labelled.

#### *Option 2 – Reject application*

Consumers: Possible restriction in the availability of imported corn products which may be produced after co-mingling of seed from MON87411.

No effect on consumers wishing to avoid GM foods, as food from MON87411 is not currently permitted in the food supply.

Potential increase in price of imported corn foods due to requirement for segregation of MON87411.

Government: Potential effect if considered inconsistent with WTO obligations but this would be in terms of trade policy rather than in government revenue.

Industry: Possible restriction on imports of corn food products if MON87411 were to be commercialised overseas.

Potential longer-term effect i.e. any successful WTO challenge has the potential to impact adversely on food industry.

As food from MON87411 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 MON87411 by other countries could limit the availability of imported corn products in the Australian and New Zealand markets.

FSANZ has decided to prepare a draft variation to Standard 1.5.2 because the potential benefits of approving the variation outweigh the potential costs, and because no public health or safety concerns resulting from consumption of food derived from MON87411 were identified in the safety assessment.

#### **2.4.1.2 Other measures**

There were no measures that could achieve the same result other than an amendment to Standard 1.5.2.

#### **2.4.1.3 Any relevant New Zealand standards**

Standard 1.5.2 applies in New Zealand.

#### **2.4.1.4 Any other relevant matters**

The Applicant has submitted applications for regulatory approval of MON87411 to a number of other countries, as listed in Table 1. To date, none has been finalised.

**Table 1: List of countries to whom applications for regulatory approval of MON87411 have been submitted**

<b>Country</b>	<b>Agency</b>	<b>Type of approval sought</b>
USA	Department of Agriculture (APHIS)	environment
	Food & Drug Administration	food/feed
Canada	Food Inspection Agency	feed
	Health Canada	food
Japan	Ministry of Health, Labour and Welfare	food
Korea	Ministry of Food and Drug Safety	food
	Rural Development Administration	feed

It is the Applicant's intention to submit applications for food/feed regulatory approvals to other countries such as China that may import corn food/feed products from countries where MON87411 will be grown.

It is the Applicant's intention that MON87411 be commercially cultivated predominantly in North America. There is currently no intention to apply for approval to cultivate this line 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.

#### **2.4.2 Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

##### **2.4.2.1 Protection of public health and safety**

Food derived from MON87411 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 MON87411 is considered as safe and wholesome as food derived from other commercial corn cultivars.

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

In accordance with existing labelling provisions, food derived from MON87411 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see Section 2.2.1). The main food products from this line are likely to contain novel DNA and novel protein and therefore are likely to require labelling.

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

The requirement for detection methodology (see Section 2.2.2) is designed to address this objective.

#### **2.4.3 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 MON87411 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. MON87411 is a new food crop designed to provide growers with an alternative pest management strategy.

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

If MON87411 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<sup>2</sup>**

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

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<sup>2</sup> Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

### 3 Draft variation

The draft variation to Standard 1.5.2 is at Attachment A. The draft variation is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

### 4 Transitional arrangements for Code Revision

FSANZ has reviewed the Code in order to improve its clarity and legal efficacy. This review was undertaken through Proposal P1025 – details of which are on the FSANZ website<sup>3</sup>. FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. A further draft revision of the Code and call for submissions was released in July 2014.

The FSANZ Board approved the proposed changes to the Code in December 2014. The new Code will commence in March 2016 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, including the variations at Attachment A, if not rejected by the Forum.

### 5 References

Codex (2004) *Principles for the risk analysis of foods derived from modern biotechnology*. Report No. CAC/GL 44-2003, Codex Alimentarius Commission, Rome.

[http://www.codexalimentarius.net/web/standard\\_list.do?lang=en](http://www.codexalimentarius.net/web/standard_list.do?lang=en).

FSANZ (2007) *Safety assessment of genetically modified foods – Guidance document*. Document prepared by Food Standards Australia New Zealand.

<http://www.foodstandards.gov.au/srcfiles/GM%20FINAL%20Sept%2007L%202.pdf>.

FSANZ (2013) *Application handbook*. Prepared by Food Standards Australia New Zealand.

<http://www.foodstandards.gov.au/foodstandards/changingthecode/applicationshandbook.cfm>.

### Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

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<sup>3</sup> <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

## Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



### Food Standards (Application A1097 – Food derived from Herbicide-tolerant and Insect-protected Corn Line MON87411) 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 A1097 – Food derived from Herbicide-tolerant and Insect-protected Corn Line MON87411) 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

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	2.22	Food derived from herbicide-tolerant and insect-protected corn line MON87411	
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## **Attachment B – Draft 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 A1097 which seeks permission for the sale and use of food derived from herbicide-tolerant and insect-protected corn line MON87411 (MON87411). The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

### **2. Purpose**

Standard 1.5.2 of the Code currently sets out the permission and conditions for the sale and use of foods produced using gene technology. Permitted foods using gene technology are listed in the Schedule to Standard 1.5.2. Food derived from MON87411 is not currently listed in the Schedule to Standard 1.5.2 and therefore is not permitted for sale or use in food. Therefore, FSANZ is proposing to vary Standard 1.5.2 by inserting into the Schedule, in relation to the commodity “Corn”, a reference to “Food derived from herbicide-tolerant and insect-protected corn line MON87411”.

### **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 A1097 will include 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 MON87411, 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 in Item numerical order in the Schedule to Standard 1.5.2 “Food derived from herbicide-tolerant and insect-protected corn line MON87411”.