

16 January 2012
[1-12]

Call for submissions – Application A1066

Food derived from Herbicide-tolerant Corn Line MON87427

FSANZ has assessed an Application made by Monsanto Australia Limited (Monsanto) to seek permission for food derived from corn line MON87427 which is genetically modified to provide tissue-selective tolerance to glyphosate, 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 its consideration of the draft food regulatory measure.

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

Under the Information Publication Scheme all submissions on applications and proposals, will be published on our website. We will not publish any material provided in-confidence. 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.

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) 27 February 2012

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.

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

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

Table of Contents

1. EXECUTIVE SUMMARY	2
2. INTRODUCTION.....	3
2.1 THE APPLICANT.....	3
2.2 THE APPLICATION	3
2.3 THE CURRENT STANDARD.....	3
2.4 REASONS FOR ACCEPTING APPLICATION.....	3
2.5 PROCEDURE FOR ASSESSMENT	3
3. SUMMARY OF THE ASSESSMENT.....	3
3.1 RISK ASSESSMENT.....	3
3.2 REGULATORY OPTIONS AND IMPACTS	4
3.2.1 <i>Cost/benefit analysis</i>	4
3.2.2 <i>Other measures</i>	7
3.2.3 <i>Relevant New Zealand standards</i>	7
3.2.4 <i>Any other relevant matters</i>	7
3.2.5 <i>Addressing FSANZ's objectives for standards-setting</i>	7
3.2.6 <i>Impact analysis</i>	10
3.3 RISK COMMUNICATION	10
3.3.1 <i>World Trade Organization (WTO)</i>	12
4. DRAFT VARIATION	12
4.1.2 <i>Implementation</i>	12
5. REFERENCES.....	13
ATTACHMENT A – DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	14
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT	16

Supporting documents

The following document which informed the assessment of this Application is available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1066food5286.cfm>

SD1: Safety Assessment Report: Application A1066 – Food Derived from Herbicide-Tolerant Corn Line MON87427

1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Limited (Monsanto) on 16 August 2011. 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), to permit the sale and use of food derived from genetically modified (GM) corn line MON87427, conferring herbicide-tolerance.

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 forms the central component in considering an application.

The safety assessment of corn line MON87427 is provided in Supporting Document 1. No potential public health and safety concerns have been identified. On the basis of the data provided in the present Application, and other available information, food derived from corn line MON87427 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

FSANZ has prepared a draft variation to the Code to include food derived from corn line MON87427 in Standard 1.5.2.

2. Introduction

2.1 The Applicant

Monsanto Australia Limited is part of Monsanto. The company is a technology provider to the agricultural and food industries.

2.2 The Application

Application A1066 – Food derived from herbicide-tolerant corn line MON87427, was submitted by Monsanto Australia Limited on 16 August 2011. It sought approval for food derived from line MON87427 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

Corn line MON87427 is tolerant to the herbicide glyphosate. Tolerance is achieved through the introduction of the *cp4 epsps* gene, from the soil bacterium *Agrobacterium* sp. expressing the protein 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS). EPSPS proteins have been widely used to confer glyphosate tolerance in a range of GM crop species. An added feature of the genetic modification in MON87427 is that the regulatory elements driving expression of the *cp4 epsps* gene permit no, or only very low, expression of the CP4 EPSPS protein in pollen tissue. This means that inbred lines containing the MON87427 transformation event can be sprayed with glyphosate at a critical developmental stage to produce male sterile female parents for use in hybrid seed production programmes.

2.3 The current Standard

Pre-market approval is necessary before food derived from any genetically modified (GM) line may enter the Australian and New Zealand food supply. Approval of GM foods under Standard 1.5.2 is contingent upon completion of a comprehensive pre-market Safety Assessment. Foods that have been assessed under the Standard, if approved, are listed in the Schedule to the Standard.

2.4 Reasons for accepting Application

The Application was accepted for assessment on the basis that:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure]

2.5 Procedure for assessment

The Application is being assessed under the General Procedure.

3. Summary of the assessment

3.1 Risk assessment

The safety assessment of corn line MON87427 is provided in Supporting Document 1 and included the following key elements:

- a characterisation of the transferred genes, their origin, function and stability in the corn genome
- the changes at the level of DNA and protein in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes
- the potential for the newly expressed proteins to be either allergenic or toxic in humans.

The assessment of corn line MON87427 was restricted to food safety and nutritional issues. Any risks related to the release into the environment of GM plants used in food production, or the safety of animal feed or animals consuming feed derived from GM plants have not been addressed in this assessment.

No potential public health and safety concerns have been identified.

On the basis of the data provided in the present Application, and other available information, food derived from corn line MON87427 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

3.2 Regulatory options and impacts

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- there are no other measures that would be more cost-effective than a variation to Standard that could achieve the same end
- any relevant New Zealand standards
- any other relevant matters.

Two regulatory options were considered: (1) rejection of the Application; or (2) preparation of a draft variation to Standard 1.5.2 to include food derived from corn line MON87427.

3.2.1 Cost/benefit analysis

A consideration of the cost/benefit of the regulatory options 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.

Option 1 – Reject application

Consumers: Possible restriction in the availability of imported corn products to those

products that do not contain corn line MON87427.

No impact on consumers wishing to avoid GM foods, as food from corn line MON87427 is not currently permitted in the food supply.

Potential increase in price of imported corn foods due to requirement for segregation of corn line MON87427.

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

Industry: Possible restriction on imports of corn food products if corn line MON87427 were to be commercialised overseas.

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

Option 2 – Develop a draft variation to Standard 1.5.

Consumers: Broader availability of imported corn products as there would be no restriction on imported foods containing corn line MON87427.

Potentially, no increase in the prices of imported foods manufactured using comingled corn products.

Appropriate labelling would allow consumers wishing to avoid certain GM corn products to do so.

Government: Benefit that if corn line MON87427 was detected in corn imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of corn line MON87427 would ensure no conflict with WTO 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 corn line MON87427 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 some food ingredients derived from corn line MON87427 would be required to be labelled.

As food from corn line MON87427 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 corn line MON87427 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 corn line MON87427 from those containing approved corn lines which would be likely to increase the costs of imported corn-derived foods. Also, to not prepare a draft variation was considered likely to be inconsistent with Australia's and New Zealand's WTO obligations.

Based on the conclusions of the safety assessments, the potential benefits of approving the variation outweighed the potential costs.

3.2.2 Other measures

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

3.2.3 Relevant New Zealand standards

Standard 1.5.2 applies in New Zealand.

3.2.4 Any other relevant matters

Monsanto submitted a food and feed safety and nutritional assessment summary for MON87427 to the US Food and Drug Administration in December 2010 and also requested a Determination of Nonregulated Status for MON 87427, including all progeny derived from crosses between MON 87427 and other corn lines, from the Animal and Plant Health Inspection Service of the US Department of Agriculture in October 2010.

Applications have also been submitted to:

- the Canadian Food Inspection Agency and Health Canada in January 2011
- the Korean Food and Drug Administration and Rural Development Administration in June 2011
- Japan's Ministry of Health, Labour, and Welfare and Ministry of Environment in June 2011 and May 2011 respectively
- the Philippines Bureau of Plant Industry in July 2011.

The Applicant has indicated that submissions are likely to be made to a number of additional governmental regulatory agencies including those in Mexico and the European Union.

It is the Applicant's intention that corn line MON87427 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. Such cultivation in Australia or New Zealand could have an impact on the environment, which would need to be independently assessed by the Office of the Gene Technology Regulator (OGTR) in Australia and the Environmental Protection Authority (EPA) in New Zealand, before commercial release in either country could be permitted.

3.2.5 Addressing FSANZ's objectives for standards-setting

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

3.2.5.1 Protection of public health and safety

Food derived from corn line MON87427 has been assessed according to the safety assessment guidelines prepared by FSANZ(2007).

No public health and safety concerns were identified in this assessment. On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from corn line MON87427 is considered as safe and wholesome as food derived from other commercial corn cultivars.

3.2.5.2 The provision of adequate information relating to food to enable consumers to make informed choices

Labelling addresses this objective set out in paragraph 18(1)(b) of the FSANZ Act. The general labelling requirements will provide consumers with information about the GM status of foods.

In accordance with general labelling provisions, food derived from corn line MON87427 would be required to be labelled as genetically modified if it contains novel DNA or novel protein.

MON87427 itself 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, contain negligible levels of any protein or DNA. Similarly, in the production process for refined corn oil, protein and DNA are likely to be reduced below the level of detection. Therefore such products derived from MON87427 would be unlikely to require labelling.

MON87427 corn products such as meal (used in bread and polenta) and grits (used in cereals) would be likely to contain detectable levels of protein and DNA, and if so, would require labelling. Sweet corn kernels containing the MON87427 event would also be likely to require labelling.

3.2.5.3 The prevention of misleading or deceptive conduct

Detection methodology

Recently, the Implementation Sub-Committee (ISC), a sub-committee of the Food Regulation Standing Committee, agreed to the formation of an Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions that would identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM applications. As part of its remit, the EAG will make recommendations to Australian and New Zealand enforcement agencies on suitable methods of analysis. To date this EAG has not yet been formed but, as part of an application, the Applicant is required to confirm there is a method of analysis that is fit-for-purpose.

The information that would be required to be given to the EAG would be the full sequence data for the insert and adjacent genomic DNA. Using this, any analytical laboratory would have the capability to develop a detection method. This sequence information has been supplied by the Applicant, although it is currently CCI and would therefore have restricted access.

Since approval to grow corn MON87427 commercially has not yet been given in any country,

food derived from this line would not yet be expected to enter the food supply.

Labelling

The labelling requirement discussed above is also relevant to the prevention of misleading or deceptive conduct.

3.2.5.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed in subsection 18(2):

- *The need for standards to be based on risk analysis using the best available scientific evidence.*

FSANZ's approach to the safety assessment of GM foods applies concepts and principles outlined in the Codex General Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2004). An Applicant for a GM food submits to FSANZ, a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the Applicant, other available resource material including published scientific literature and general technical information is used in the safety assessment.

- *The promotion of consistency between domestic and international food standards.*

FSANZ assesses the safety of GM foods in accordance with internationally established scientific principles and guidelines developed through the work of the Organisation for Economic Cooperation and Development, Food and Agriculture Organization of the United Nations, World Health Organization and the Codex Alimentarius Commission. These principles and guidelines are, however, applied within the context of the Australian and New Zealand food regulatory framework.

- *The desirability of an efficient and internationally competitive food industry.*

The inclusion of genetically modified 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.

- *The promotion of fair trading in food.*

The cost/benefit analysis in Section 3.2.1, lists a number of considerations that address fair trading with respect to corn line MON87427.

- *Any written policy guidelines formulated by the Ministerial Council.*

For GM foods, there are no relevant guidelines.

3.2.6 Impact analysis

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010 (reference 12065), provided an exemption from the need for the OBPR to be informed about GM food applications.

3.3. Risk communication

FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions are notified via media release and through FSANZ's social media tools and

the publication *Food Standards News*.

Subscribers and interested parties are also notified about the availability of reports for public comment.

The process by which FSANZ considers standard 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.

Since 1 May 2011, FSANZ has been placing all new applications on the FSANZ website. Over time applications received before 1 May 2011, particularly those that have attracted a lot of public interest, will be added to the website.

Application A1066 is already available on the website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1066food5286.cfm>.

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

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 COAG Legislative and Governance Forum on Food Regulation¹ (FOFR). If the approval of food derived from herbicide-tolerant corn line MON87427 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.

3.3.1 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.

There are no relevant international standards and amending the Code to permit food derived from herbicide-tolerant corn line MON87427 is unlikely to have a significant effect on international trade as it would permit food derived from herbicide-tolerant corn line MON87427 to be imported into Australia and New Zealand and sold, where currently sale is prohibited. Accordingly, 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.

4. Draft variation

The draft variation to Standard 1.5.2 is at Attachment A.

A draft Explanatory Statement is at Attachment B.

4.1.2 Implementation

The variation will take effect on gazettal

¹ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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.

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%20_2_.pdf.

Attachments

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

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



Food Standards (Application A1066 – Food derived from Herbicide-tolerant Maize MON87427) Variation

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 X

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Application A1066 – Food derived from Herbicide-tolerant Maize MON87427) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

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

3 Commencement

These variations commence **on the date of gazettal**.

SCHEDULE

[1] **Standard 1.5.2** is varied by inserting in numerical order in the Schedule–

	2.x	Food derived from herbicide-tolerant corn line MON87427	
--	-----	---	--

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 A1066 which seeks permission for the sale and use of food derived from herbicide-tolerant corn line MON87427. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to a Standard.

2. Purpose and operation

As it is not listed in the Schedule to Standard 1.5.2, food derived from corn line MON87427 is not currently permitted for sale or use in food. Therefore, FSANZ is proposing to vary Standard 1.5.2 by including food derived from corn line MON87427 in the Schedule.

3. Documents incorporated by reference

The variation does 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 A1066 will include one round of public consultation following an assessment and the preparation of a draft variation. A Call for Submissions (which includes the draft Standard) will be released for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the use of food derived from corn line MON87427, 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

This item adds food derived from corn line MON87427 into the Schedule to Standard 1.5.2.