

16 February 2016
[04–16]

Approval Report – Application 1114

Food derived from High Yield Corn Line MON87403

FSANZ has assessed an Application made by Monsanto Australia Ltd seeking permission for food derived from corn line MON87403, which is genetically modified to have increased ear biomass at an early reproductive phase compared to conventional corn.

On 16 September 2015, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received five submissions.

FSANZ approved the draft variation on 10 February 2016. The Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 15 February 2016.

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

Table of Contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD	3
1.4 REASONS FOR ACCEPTING APPLICATION	3
1.5 PROCEDURE FOR ASSESSMENT	3
1.6 DECISION	3
2 SUMMARY OF THE FINDINGS	4
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	4
2.1.1 <i>General Issues</i>	4
2.2 SAFETY ASSESSMENT	5
2.3 RISK MANAGEMENT	6
2.3.1 <i>Labelling</i>	6
2.3.2 <i>Detection methodology</i>	6
2.4 RISK COMMUNICATION.....	6
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS	7
2.5.1 <i>Section 29</i>	7
2.5.2 <i>Subsection 18(1)</i>	9
REFERENCES	10
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE REVISED <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> (TO COMMENCE ON 1 MARCH 2016).....	11
ATTACHMENT B – EXPLANATORY STATEMENT	13

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/A1114-GMCornLineMON87403.aspx>

SD1 Safety Assessment Report (at Approval)

Executive summary

All references to the *Australia New Zealand Food Standards Code* (the Code) in this assessment summary and related SDs are to the revised Code which will take effect on 1 March 2016.

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Ltd on 5 June 2015. The Applicant requested a variation to previous Standard 1.5.2 – Food produced using Gene Technology, which in the revised Code represents a variation to Schedule 26. The variation sought is to permit the sale and use of food derived from a genetically modified (GM) corn line that is modified to have increased ear biomass (higher yield) at an early reproductive phase compared to conventional corn.

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in section 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 high yield corn line MON87403 (also referred to as MON87403) 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 MON87403 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 high yield corn line MON87403.

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 A1114 was submitted by Monsanto Australia Ltd on 5 June 2015. It sought approval for food derived from high yield corn line MON87403 with OECD Unique Identifier MON-87403-1 (also referred to as MON87403).

MON87403 has been modified to have increased ear biomass at an early reproductive phase compared to conventional corn. This modification is achieved through expression of a truncated *ATHB17* (*Arabidopsis thaliana* homeobox-leucine zipper protein 17) transcription factor encoded by the *ATHB17* gene from *Arabidopsis thaliana*.

1.3 The current Standard

FSANZ completed a review of the Code in 2015 and the revised Code will commence on 1 March 2016. Previous Standard 1.5.2 which set out permissions 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 including 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 Schedule 26.

Standard 1.5.2 in the revised Code 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 or if the food is listed in subsections S26-3(2) and (3) of Schedule 26.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved without change.

The approved draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

2.1.1 General Issues

A total of five submissions were received of which two were opposed to the proposed draft variation to Schedule 26. Responses to four general and relevant issues raised or implied in the two opposed submissions, are provided in Table 1. It is noted that issues raised about herbicide tolerance traits and RNA interference (RNAi) are not relevant to MON87403.

Table 1: Summary of general issues raised in submissions

Issue	Raised by	FSANZ response
<p>Lack of consideration of long term feeding studies in the safety assessment</p>	<ul style="list-style-type: none"> Physicians & Scientists for Global Responsibility (PSGR) 	<p>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 MON87403 showed that it is compositionally equivalent to grain from conventional corn varieties.</p> <p>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/role_of_animal_feedings3717.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 MON87403, 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).</p>
<p>Potential for the formation of allergens and toxins in GM foods</p>	<ul style="list-style-type: none"> PSGR 	<p>The occurrence of allergies in people eating Western diets is attributed to major allergens already in the food supply – e.g. milk, eggs and nuts, particularly peanuts. These commonly allergenic foods are not associated with GM commodities. There is no credible scientific basis to support the notion that food allergies are linked to the introduction of any GM crops or that allergens can arise spontaneously as a result of the genetic modification process (Goodman and Tetteh 2011).</p> <p>Similarly, there is no evidence that toxins can arise <i>de novo</i> as a result of the genetic modification process (Bartholomaeus et al. 2013)</p> <p>Any novel proteins likely to be present in a GM food undergo individual assessment for both allergenicity and toxicity.</p>

Issue	Raised by	FSANZ response
<p>The safety of ingesting transgenes</p> <p>Horizontal gene transfer</p>	<ul style="list-style-type: none"> PSGR 	<p>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.</p> <p>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</p>
<p>Transgenic corn is of lower nutritional quality than conventional corn. Conventional corn contains 437 times more calcium, 56 times more magnesium and 7 times more manganese than transgenic corn</p>	<ul style="list-style-type: none"> PSGR 	<p>The compositional analysis provided in Section 5 of Supporting Document 1 indicates that grain from MON87403 is compositionally equivalent (including in calcium, magnesium and manganese) to grain from conventional corn cultivars.</p>

2.2 Safety assessment

The safety assessment of MON87403 is provided in the supporting document (SD1) and included the following key elements:

- a characterisation of the transferred genetic material, its origin, function and stability in the corn genome
- characterisation of novel nucleic acids and protein in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes
- the potential for any newly expressed protein to be either allergenic or toxic in humans.

No potential public health and safety concerns have been identified. Based on the data provided in the present Application, and other available information, food derived from MON87403 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

The assessment of MON87403 was restricted to human food safety and nutritional issues. This assessment therefore does not address any risks to the environment that may occur as the result of growing GM plants used in food production, or any risks to animals that may consume feed derived from GM plants.

In addition, minor typographical errors in the SD1 released with the Call for Submissions have been corrected.

2.3 Risk management

2.3.1 Labelling

Standard 1.5.2 generally requires food produced using gene technology to be labelled as 'genetically modified' if it contains novel DNA or novel protein. That is, DNA or protein that is different to that found in the counterpart part produced without gene technology.

MON87403 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 MON87403 would be unlikely to require labelling.

MON87403 products such as meal (used in bread and polenta) and grits (used in cereals) would be likely to contain novel protein or novel DNA, and if so, would require labelling. Sweet corn kernels containing the MON-87403-1 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-Committee² to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food derived from gene technology (GM applications).

The EAG indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the Applicant for A1114 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 16 September and 28 October 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 five 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.

² Now known as the Implementation Subcommittee for Food Regulation

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 A1114, 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 A1114, 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 MON87403 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 MON87431 has been assessed as being as safe as food from conventional cultivars of corn.

Broader availability of imported corn products since if MON87403 is approved for commercial growing in other countries, there would be no restriction on imported foods containing this line.

For those corn line MON87403 products containing novel DNA or novel protein, appropriate labelling would allow consumers wishing to avoid these products to do so.

If MON87403 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 MON87403 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 MON87403 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 MON87403 would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of seed of MON87403, 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 MON87403 would require the 'genetically modified' labelling statement if they contain novel DNA or novel protein.

As food from MON87403 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 MON87403 by other countries could limit the availability of imported corn products in the Australian and New Zealand markets.

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

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of Application A1114.

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 MON87403 to a number of other countries, as listed in Table 2. The status of each application is indicated.

Table 2: List of other countries to whom applications for regulatory approval of MON87403 have been submitted

Country	Agency	Type of approval sought	Status
USA	U.S. Department of Agriculture	environment	Under assessment
	Food & Drug Administration	food/feed	Authorised 19/06/2015
Canada	Food Inspection Agency	environment/feed	Under assessment
	Health Canada	food	Under assessment

Country	Agency	Type of approval sought	Status
Japan	Ministry of Health, Labour and Welfare	food	Under assessment
	Ministry of Agriculture, Forestry & Fisheries	feed	Under assessment
Korea	Ministry of Food and Drug Safety	food	Under assessment
	Rural Development Administration	feed	Under assessment
Taiwan	Ministry of Health & Welfare	food	Under assessment
Europe	European Food Safety Authority	food	Under assessment

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

It is the Applicant's stated intention that lines containing event MON-87403-1 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 MON87403 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 MON87403 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 MON87403 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 MON87403 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. MON87403 is a new food crop designed to have increased yield over conventional corn varieties.

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

Not applicable.

- **any written policy guidelines formulated by the Ministerial Council³**

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

References

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

FSANZ (2007) Safety assessment of genetically modified foods - guidance document. Document prepared by Food Standards Australia New Zealand.
<http://www.foodstandards.gov.au/publications/Pages/Safety-Assessment-of-Genetically-Modified-Foods-Guidance-Document-.aspx>

FSANZ (2013) Application handbook. Prepared by Food Standards Australia New Zealand.
<http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

Goodman RE, Tetteh AO (2011) Suggested improvements for the allergenicity assessment of genetically modified plants used in foods. *Current Allergy and Asthma Reports* 11:317–324

Attachments

- A. Approved draft variation to the revised *Australia New Zealand Food Standards Code* (to commence on 1 March 2016)
- B. Explanatory Statement

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)

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



Food Standards (Application A1114 – Food derived from High Yield Corn Line MON87403) 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 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 A1114 – Food derived from High Yield Corn Line MON87403) 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 Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule 26 is varied by inserting in the table to subsection S26—3(4) in alphabetical order under item 2

(y) high yield corn line MON87403

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 A1114 which seeks permission for the sale and use of food derived from high yield corn line MON87403 (MON87403). 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 Regulation⁴, 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 sunseting under the *Legislative Instruments Act 2003*.

2. Purpose

The variation inserts a reference to high yield corn line MON87403 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 A1114 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 MON87403, 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.

⁴ convening as the Australia and New Zealand Food Regulation Ministerial Council

6. Variation

Item [1] inserts paragraph (y) into item 2 in the table to subsection S26—3(4) of Schedule 26. The new item refers to high yield corn line MON87403. 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.