

15 July 2015
[14–15]

Call for submissions – Application A1110

Food derived from Insect-protected Soybean Line MON87751

FSANZ has assessed an Application made by Monsanto Australia Ltd seeking permission for food derived from soybean line MON87751, which is genetically modified to provide protection against key lepidopteran pests of soybean. A draft food regulatory measure has been prepared. 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.

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) 26 August 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.

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/A1110GMsoybeanMON87751.aspx>

SD1 Safety Assessment Report

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Ltd on 20 February 2015. 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) soybean line that is protected against lepidopteran pests.

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 insect-protected soybean line MON87751 (also referred to as MON87751) 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 MON87551 is considered to be as safe for human consumption as food derived from conventional soybean cultivars.

FSANZ has prepared a draft variation to Schedule 26 of the revised Code (commencing on 1 March 2016) that includes a reference to food derived from insect-protected soybean line MON87751.

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 A1110 was submitted by Monsanto Australia Ltd on 20 February 2015. It seeks approval for food derived from insect-protected soybean line MON87751 with OECD Unique Identifier MON-87751-7 (also referred to as MON87751). MON87751 has been modified such that it is protected against lepidopteran pests of soybean.

Protection against lepidopteran insect pests is achieved through expression of two Cry proteins (Cry1A.105 and Cry2Ab2) encoded by the *cry1A.105* and *cry2Ab2* genes derived from the common soil bacterium *Bacillus thuringiensis*. The safety of the Cry1A.105 and Cry2Ab2 proteins has previously been assessed by FSANZ.

1.3 The current Standard

FSANZ completed a review of the Code in 2015 and the revised Code will commence on 1 March 2016. Current Standard 1.5.2 which sets out the permission and conditions for the sale and use of food produced using gene technology (a GM food), which is replicated in the revised Code in Schedule 26.

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 and inclusion in Schedule 26 of the revised Code 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. GM foods and ingredients (including food additives and processing aids from GM sources) must be identified on labels with the words 'genetically modified', if novel DNA and/or novel protein (as defined in Standard 1.5.2) is present in the final food, or the food has altered characteristics. In the latter case the Standard also allows for 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) 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 is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Safety assessment

The safety assessment of MON87751 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 soybean 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 MON87751 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 MON87751 is considered to be as safe for human consumption as food derived from conventional soybean cultivars.

2.2 Risk management

2.2.1 Labelling

In accordance with Standard 1.5.2, food derived from MON87751 would be required to be labelled as 'genetically modified' if it contains novel DNA and/or novel protein, or if it has altered characteristics. MON87751 does not have altered characteristics.

MON87751 is intended primarily for use as a broad-acre commodity (field soybean) to produce products derived from cracked soybeans, and is not intended for vegetable or garden purposes where food-grade products may include tofu, soybean sprouts, soy milk, and green soybean (e.g. edamame). This latter type of soybean generally has a different size, flavour and texture to field soybean. The main food product from field soybean is refined oil. Processing during production means novel protein and novel DNA are not likely to be present in the oil; in the absence of novel protein and novel DNA, refined oil from MON87751 would be exempt from labelling under section 1.5.2-4 of Standard 1.5.2 in the revised Code. Other products such as protein concentrate, protein isolate and textured flour are likely to contain novel protein and/or novel DNA and if so, would 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-Committee¹ 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).

¹ Now known as the Implementation Subcommittee for Food Regulation

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 A1110 and hence satisfies 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.

There are not any relevant international standards, and amending the Code to permit food derived from MON87751 is unlikely to have a significant effect on international trade as it would permit food derived from line MON87551 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.

A 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 MON87751 being approved for growing in other countries (see Table 1) 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 2.4.1.4 below).

Option 1 – Prepare a draft variation to Schedule 26

Consumers: Broader availability of imported soybean products since MON87751 is approved for commercial growing in other countries, and there would therefore be no restriction on imported foods containing this line.

Appropriate labelling would allow consumers wishing to avoid soybean line MON87751 products containing novel DNA or novel protein to do so.

Since MON87751 is approved for commercial growing in overseas countries it can be used in the manufacture of products using co-mingled soybean seed. This means that there would be no cost involved in having to exclude MON87751 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 soybean seed.

Government: If MON87751 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.

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 MON87751 would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of seed of MON87751, 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 soybean products or imported foods manufactured using soybean derivatives.

There may be additional costs to the food industry as some food ingredients derived from MON87751 would be required to be labelled.

Option 2 – Reject application

Consumers: Possible restriction in the availability of imported soybean products which may be produced after co-mingling of seed from MON87751.

No effect on consumers wishing to avoid GM foods, as food from MON87751 is not currently permitted in the food supply.

Potential increase in price of imported soybean foods due to requirement for segregation of MON87751.

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 soybean food products, since MON87751 is already commercialised overseas.

As food from MON87751 has been found to be as safe as food from conventional cultivars of soybean, not preparing a draft variation would offer little benefit to consumers, as approval of MON87751 by other countries could limit the availability of imported soybean products in the Australian and New Zealand markets.

FSANZ has decided to prepare a draft variation to Schedule 26 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 MON87751 were identified in the safety assessment.

2.4.1.2 Other measures

There are no measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure varied as a result of Application A1110.

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 MON87751 to a number of other countries, as listed in Table 1. Some of these have been finalised as indicated.

Table 1: List of countries to whom applications for regulatory approval of line 4114 have been submitted

Country	Agency	Type of approval sought	Status
USA	U.S. Department of Agriculture	environment	Authorised 17/10/2014
	Food & Drug Administration	food/feed	Consultation completed 27/05/2015
	Environmental Protection Agency	environment	Authorised 27/04/2015
Canada	Food Inspection Agency	environment/feed	Authorised 31/10/2014
	Health Canada	food	Authorised 31/10/2014
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
China	Ministry of Agriculture	food	Under assessment
Taiwan	Ministry of Health & Welfare	food/feed	Under assessment
Argentina	National Advisory Commission on Agriculture Biotechnology (CONABIA)	environment	Under assessment
	National Service of Agriculture & Cattle Sanitary & Food Safety (SENASA)	food/feed	Under assessment
Brazil	National Biosafety technical Committee (CTNBio)	food	Under assessment
Europe	European Food Safety Authority (EFSA)	food	Under assessment

It is the Applicant's stated intention that lines containing event MON87751 be commercially cultivated predominantly in South America (e.g. Argentina and Brazil). There is currently no intention to apply for approval to cultivate lines containing this event in either Australia or New Zealand. Cultivation in Australia or New Zealand would require independent assessment and approval by the Office of the Gene Technology Regulator in Australia and by the Environmental Protection Authority in New Zealand.

2.4.2 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 MON87751 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 MON87751 is considered as safe and wholesome as food derived from other commercial soybean 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 to enable informed consumer choice, food derived from MON87751 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see Section 2.2.1).

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 Principles for the Risk Analysis of Foods derived from Biotechnology (Codex 2004). Based on these principles, the risk analysis undertaken for MON87751 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. MON87751 is a new food crop designed to expedite future breeding efforts and provide growers with an alternative pest management strategy.

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

Since MON87751 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 Council²**

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

3 Draft variation

The proposed draft variation is only for the revised Code since it comes into operation and replaces the current Code on 1 March 2016. FSANZ believes it is unnecessary to amend the

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

current Code as gazetted is expected to be close to this time, if the Board eventually approves the variation and no review of that decision is requested by Ministers. The draft variation to the revised Code is at Attachment A and is intended to take effect on 1 March 2016.

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 References

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>

Attachments

- A. Draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)
- B. Draft Explanatory Statement

Attachment A – Draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)



Food Standards (Application A1110 – Food derived from Insect-protected Soybean Line MON87751) 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 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**.

1 Name

This instrument is the *Food Standards (Application A1110 – Food derived from Insect-protected Soybean Line MON87751) Variation*.

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

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

3 Commencement

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

SCHEDULE

[1] Item 7 in the Table to subsection S26—3(4) of Schedule 26 is varied by inserting after item 7(o)

“

(p) insect-protected soybean line MON87751

”

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 A1110 which seeks permission for the sale and use of food derived from insect-protected soybean line MON87751 (MON87751). The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The variation inserts a reference to insect-protected soybean line MON87751 into Schedule 26 of the Code in order to permit the sale, or use in food, of food derived from that soybean 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 A1110 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 MON87751, 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 item 7(p) into the Table to subsection S26—3(4) of Schedule 26. The new item refers to insect-protected soybean line MON87751. The effect of the variation is to permit in accordance with Standard 1.5.2 the sale and use of food derived from that soybean line.