

**21 June 2018**

**[50-18]**

Approval report – Application A1154

Food derived from insect-protected cotton line MON88702

Food Standards Australia New Zealand (FSANZ) has assessed an Application made by Monsanto Australia Limited to seek approval for food derived from cotton line MON88702, genetically modified to provide protection from piercing and sucking insects.

On 18 December 2017, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 7 June 2018. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ’s decision on 18 June 2018.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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**Supporting document**

The [following document](http://www.foodstandards.gov.au/code/applications/Pages/ApplicationA1154Food-derived-from-insect-protected-cotton-line-MON88702.aspx)[[1]](#footnote-2) which informed the assessment of this Application is available on the FSANZ website:

SD1 Safety Assessment Report

# Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Limited on 14 September 2017 requesting a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to include food derived from a new genetically modified (GM) cotton (*Gossypium hirsutum*) line, MON88702. This cotton line has been genetically modified for protection from piercing and sucking insect pests.

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 MON88702 is provided in Supporting Document 1. No potential public health and safety concerns have been identified in the course of the safety assessment. Based on the data provided and other available information, food derived from cotton line MON88702 is considered to be as safe for human consumption as food derived from conventional cotton cultivars.

The FSANZ Board has approved the draft variation to Schedule 26 that inserts a reference into that Schedule to food derived from cotton line MON88702. The effect of the variation is to permit the use or sale of food derived from that cotton line in accordance with Standard 1.5.2.

# 1 Introduction

## 1.1 The Applicant

Monsanto Australia Limited (Monsanto) is a technology provider to sectors including agriculture.

## 1.2 The Application

Application A1154 was submitted on 14 September 2017. It seeks a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to include food from a new genetically modified (GM) cotton (*Gossypium hirsutum*) line, MON88702. This cotton line has been genetically modified for protection from piercing and sucking insect pests, belonging to the hemiptera and thysanoptera orders.

Protection from the piercing and sucking insect pests is achieved by expression of a modified Cry51Aa2 (designated mCry51Aa2) insecticidal crystalline (Cry) protein, encoded by the gene *mCry51Aa2* that was derived from the soil bacterium *Bacillus thuringiensis*. FSANZ has previously approved a large number of Applications where *B. thuringiensis* Cry proteins have been introduced into crops for insect-protection but this is the first Application based on the Cry51 protein.

The Applicant has indicated that food derived from MON88702 may be used in food as cottonseed oil and linters. Cottonseed oil may be used in foods such as frying oil, salad and cooking oil, and as an ingredient in mayonnaise, salad dressing, shortening, and margarine.

Linters are the short fibres that coat the seeds and are a by-product of oil extraction from cotton seeds. Linters can be processed into forms of cellulose that may be used in certain food additives, for example anticaking agents and thickeners. Other food uses include casings for processed meats.

## 1.3 The current Standard

Pre-market approval is necessary before a genetically modified (GM) food may enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment. Standard 1.5.2 – Food produced using gene technology, sets out the permission and conditions for the sale of food that consists of, or has as an ingredient, a food produced using gene technology (a GM food). Foods that have been assessed and permitted are listed in Schedule 26.

Section 1.5.2—4 of Standard 1.5.2 also contains specific labelling provisions for approved GM foods. Subject to certain exceptions listed below, GM foods and ingredients (including food additives and processing aids from GM sources) must be identified on labels with the words ‘genetically modified’, if novel DNA or novel protein (as defined in Standard 1.5.2) is present in the food.

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

The requirement to label food as ‘genetically modified’ does not apply to GM food that:

* has been highly refined (other than food that has been altered), where the effect of the refining process is to remove novel DNA or novel protein
* is a substance used as a processing aid or a food additive, where novel DNA or novel protein from the substance does not remain present in the final food
* is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%)
* is intended for immediate consumption and which is prepared and sold from food premises and vending machines, including restaurants, take away outlets, caterers, or self-catering institutions
* is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient.

If the GM food for sale is not required to bear a label, the labelling information in section 1.5.2—4 must accompany the food or be displayed in connection with the display of the food (in accordance with subsections 1.2.1—9(2) and (3) of Standard 1.2.1 (Requirements to have labels or otherwise provide information)).

## 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 variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

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

# 2 Summary of the findings

## 2.1 Summary of submissions

A total of two submissions were received and both supported the draft variation. The submissions came from the New Zealand Ministry for Primary Industries and the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources.

## 2.2 Safety assessment

In conducting a safety assessment of food derived from MON88702, a number of criteria have been addressed including: a characterisation of the transferred gene sequences, their origin, function and stability in the cotton genome; the changes at the level of DNA and protein in the whole food; compositional analyses and evaluation of intended and unintended changes.

The assessment of MON88702 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. Cotton plants containing the MON88702 transformation event have been granted a limited and controlled release license by the OGTR in 2017 ([DIR 147](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir147)[[2]](#footnote-3)), which required an assessment of the environmental impact. The mCry51Aa2 protein has also been granted a research permit in 2017 by the Australian Pesticide and Veterinary Medicine Authority (APVMA) coinciding with the OGTR licence. The APVMA also performs a risk analysis to determine the impact of the chemical on humans, plants and animals in the environment. Should cultivation in New Zealand be sought, this would require an independent assessment by the Environmental Protection Authority in New Zealand (NZ EPA).

Some changes were made in the SD1 released with the call for submissions to correct minor errors.

No potential public health and safety concerns have been identified.

Based on the data provided in the Application, and other available information, FSANZ has assessed that food derived from MON88702 is as safe for human consumption as food derived from conventional cotton cultivars.

## 2.3 Risk management

### 2.3.1 Requirement to be labelled as ‘genetically modified’

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food derived from MON88702 will be required to be labelled as ‘genetically modified’ if it contains novel DNA or novel protein; or is listed in subsections S26—3(2) and (3) of Schedule 26 as being subject to the condition that the labelling must comply with section 1.5.2—4 of Standard 1.5.2 (such food has altered characteristics). FSANZ has determined that food derived from MON88702 does not have altered characteristics.

Cottonseed oil and linters are the major products of MON88702 intended for human consumption. Cottonseed oil is unlikely to contain novel DNA or novel protein due to the extensive refining process used to extract the oil from the seed. However, if novel DNA or novel protein is present, the labelling statement will be required.

Cottonseed linters are also highly purified and unlikely to contain novel DNA or novel protein (linters are essentially pure cellulose), therefore products containing linters from MON88702 are unlikely to require labelling. Similarly, the presence of novel DNA or novel protein will trigger the labelling requirement.

### 2.3.2 Detection methodology

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions, was formed by the Food Regulation Standing Committee’s Implementation Sub-Committee[[3]](#footnote-4) to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food produced using 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 A1154.

## 2.4 Risk communication

### 2.4.1 Consultation

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 requested 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 18 December 2017 and 14 February 2018. 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.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application.

Every submission on this Application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of the safety assessment.

Documents relating to Application A1154, including submissions received, are available on the FSANZ website.

## 2.5 FSANZ Act assessment requirements

### 2.5.1 Section 29

#### 2.5.1.1 Consideration of costs and benefits

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 GM foods (ref 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 MON88702 being approved for growing in other countries since the Applicant has only been granted permission for a limited and controlled release by the OGTR in Australia (DIR 147). Cultivation in New Zealand would require separate regulatory approval (see section 2.5.1.4).

Option 1 was selected.

#### Option 1 – Approve the draft variation to Schedule 26

*Community:* Food containing event MON88702 has been assessed as being as safe as food from conventional lines of cotton.

There would be broader availability of imported cotton products since, if MON88702 is approved for commercial growing in other countries, there would be no restriction on imported foods containing this line.

For those MON88702 food products containing novel DNA or novel protein, required labelling would allow consumers wishing to avoid these products to do so.

If MON88702 is approved for commercial growing in either overseas countries or Australia it could be used in the manufacture of products using co-mingled cotton seed. This means that there would be no cost involved in having to exclude MON88702 seed from co-mingling and hence that there would be no consequential need to increase the prices of foods that are manufactured using co-mingled cotton seed.

*Government:* Approval would avoid any conflict with WTO obligations. As mentioned above, food from MON88702 has been assessed as being as safe as food from conventional lines of cotton.

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 MON88702 would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of seed of MON88702 from conventional cotton seed, as for any GM crop, will be driven by industry, based on market preferences. Implicit in this will be a due regard to the cost of segregation.

Retailers may be able to offer a broader range of cotton products or imported foods manufactured using cotton derivatives.

There may be additional costs to the food industry as food ingredients derived from MON88702 would require the ‘genetically modified’ labelling statement if they contain novel DNA or novel protein.

*Option 2 – reject the draft variation to Schedule 26*

As food derived from MON88702 has been found to be as safe as food from conventional counterparts, not preparing a draft variation would offer little relative benefit to consumers, government and industry.

#### 2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than the proposed measure.

#### 2.5.1.3 Any relevant New Zealand standards

Standard 1.5.2 and Schedule 26 apply in both Australia and New Zealand. There is no relevant New Zealand only standard.

#### 2.5.1.4 Any other relevant matters

The Applicant has submitted applications for regulatory approval of MON88702 to a number of other countries, as listed in Table 1.

**Table 1: Updated list of countries to whom applications for regulatory approval of MON88702 have been submitted**

| **Country** | **Agency** | **Type of approval sought** | **Status** |
| --- | --- | --- | --- |
| United States of America | Environmental Protection Agency | Temporary tolerance exemption | Approved 2017 |
| Seed Increase registration | Approved 2018 |
| Permanent tolerance exemption | Approved 2018 |
| Food and Drug Administration | Food and feed | Under review |
| Canada | Health Canada | Food | Under review |
| Canadian Food Inspection Agency | Feed/environment | Under review |
| Australia | Office of the Gene Technology Regulator | Limited and Controlled release | Approved 2017 |
| Australian Pesticides And Veterinary Medicines Authority | Research permit for mCry51Aa2 | Approved 2017 |
| Japan | Ministry of Health, Labor and Welfare | Food | Under review |
| Ministry of Agriculture, Forestry and Fisheries | Feed | Under review |
| Korea | Ministry of Food and Drug Safety | Food | Under review |
| Rural Development Administration | Feed | Under review |
| Taiwan | Taiwan Food and Drug Administration | Food | Under review |
| Council of Agriculture | Feed | Under review |

The Applicant has permission for a limited and controlled release of cotton lines containing the MON88702 event in Australia from the OGTR (DIR147) and has a research permit for the novel Bt protein from the APVMA. Should cultivation in New Zealand be sought, this would require assessment by the Environmental Protection Authority in New Zealand (NZ EPA). The Applicant has indicated that the initial commercial cultivation of cotton lines containing the MON88702 event would be based in the US.

Other relevant matters are considered below.

### 2.5.2. Subsection 18(1)

FSANZ has had regard to 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 MON88702 has been assessed based on the data requirements provided in the FSANZ [*Application Handbook*](http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx)*[[4]](#footnote-5)* which, in turn reflect internationally-accepted GM food safety assessment guidelines. No public health and safety concerns were identified in this assessment. Based on the available evidence, including detailed studies provided by the Applicant, FSANZ has assessed that food derived from MON88702 is as safe and wholesome as food derived from other commercial cotton lines.

#### 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 in the Code, food derived from MON88702 will be required to be labelled as ‘genetically modified’ if it contains novel DNA or novel protein (see Section 2.3.1). This will enable consumers to make informed choices in relation to such food.

#### 2.5.2.3 The prevention of misleading or deceptive conduct

The provision of sequence information by the Applicant (Section 2.3.2) will permit the detection of food derived from MON88702 and therefore addresses 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 MON88702 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 Applicant, 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. MON88702 is a new food crop designed to provide growers with an alternative pesticidal mode of action for cotton farming systems.

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

Issues, related to consumer information and safety, are considered in Section 2.2 and 2.3 above.

* **any written policy guidelines formulated by the Forum on Food Regulation**

No specific policy guidelines have been developed.

# 3 References

Codex (2004) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome. [http://www.fao.org/fao-who-codexalimentarius/ standards/list-of-standards/en/](http://www.fao.org/fao-who-codexalimentarius/%20standards/list-of-standards/en/)

**Attachments**

A. Approved draft variation to the *Australia New Zealand Food Standards Code*

B. Explanatory Statement

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



**Food Standards (Application A1154 –** **Food derived from insect-protected cotton line MON88702) 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 the Delegate]

Scott Crerar

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 A1154 – Food derived from Insect-protected Cotton Line MON88702) 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] Schedule 26** is varied by inserting in the table to subsection S26—3(4) in alphabetical order under item 3

|  |  |  |
| --- | --- | --- |
|  |  | (p) insect-protected cotton line MON88702 |

## 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 A1154 which seeks approval for food derived from cotton line MON88702, genetically modified to provide protection from piercing and sucking insects. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation of a standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislation Act 2003*.

**2. Purpose**

The purpose of this instrument is to amend the table to subsection S26—3(4) of Schedule 26 of the Code (permitted food produced using gene technology and conditions) to permit the use or sale of food derived from the insect-protected cotton line MON88702.

**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 A1154 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 18 December 2017 for an eight-week consultation period.

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 genetically modified foods (ref 12065).

**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 new paragraph (p) into item 3 in the table to subsection S26—3(4) in Schedule 26. The new paragraph refers to ‘insect-protected cotton line MON88702’. The effect of the variation is to permit the use or sale of food derived from that cotton line in accordance with Standard 1.5.2.

1. <http://www.foodstandards.gov.au/code/applications/Pages/ApplicationA1154Food-derived-from-insect-protected-cotton-line-MON88702.aspx> [↑](#footnote-ref-2)
2. <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir147> [↑](#footnote-ref-3)
3. Now known as the Implementation Subcommittee for Food Regulation [↑](#footnote-ref-4)
4. <http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx> [↑](#footnote-ref-5)