

**5 November 2013**

**[20-13]**

Approval Report – Application A1080

Food derived from Herbicide-tolerant Cotton Line MON88701

---

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Monsanto Australia Limited seeking permission for food derived from cotton line MON88701, which is genetically modified to provide tolerance to two herbicides: dicamba and glufosinate ammonium.

On 19 July 2013, FSANZ sought submissions on a draft variation to Standard 1.5.2 and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation to the Standard on 30 October 2013. The COAG Legislative and Governance Forum on Food Regulation<sup>1</sup> (the Forum) was notified of FSANZ's decision on 4 November 2013.

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

---

<sup>1</sup> Previously known as the Australia and New Zealand Food Regulation Ministerial Council

# Table of Contents

<b>1. EXECUTIVE SUMMARY .....</b>	<b>2</b>
<b>2. INTRODUCTION .....</b>	<b>3</b>
2.1 THE APPLICANT S.....	3
2.2 THE APPLICATION .....	3
2.3 THE CURRENT STANDARD .....	3
2.4 REASONS FOR ACCEPTING THE APPLICATION .....	3
2.5 PROCEDURE FOR ASSESSMENT.....	3
2.6 DECISION .....	4
<b>3. SUMMARY OF THE FINDINGS.....</b>	<b>4</b>
3.1 RISK ASSESSMENT .....	4
3.2 RISK MANAGEMENT .....	4
3.2.1 <i>Labelling</i> .....	4
3.2.2 <i>Detection methodology</i> .....	5
3.2.3 <i>Summary of submissions</i> .....	5
3.3 RISK COMMUNICATION .....	8
<b>4. REASONS FOR DECISION .....</b>	<b>8</b>
4.1 SECTION 29.....	9
4.1.1 <i>Cost/benefit analysis</i> .....	9
4.1.2 <i>Other measures</i> .....	10
4.1.3 <i>Relevant New Zealand standards</i> .....	10
4.1.4 <i>Any other relevant matters</i> .....	10
4.2 ADDRESSING FSANZ'S OBJECTIVES FOR STANDARDS SETTING .....	10
4.2.1 <i>Protection of public health and safety</i> .....	11
4.2.2 <i>The provision of adequate information relating to food to enable consumers to make informed choices</i> 11	
4.2.3 <i>The prevention of misleading or deceptive conduct</i> .....	12
4.3 IMPLEMENTATION .....	12
<b>5. REFERENCES.....</b>	<b>12</b>
ATTACHMENT A – APPROVED VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> .....	14
ATTACHMENT B – EXPLANATORY STATEMENT .....	16

## Supporting documents

The following document used to prepare this Report is available on the FSANZ website at <http://www.foodstandards.gov.au/code/applications/Pages/A1080-Food-derived-from-Herbicide-tolerant-Cotton-Line-MON88701.aspx>

SD1: Safety Assessment (at Approval)

# 1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Limited on 21 January 2013. 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) cotton line MON88701, conferring tolerance to two herbicides.

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 central to considering an application.

The safety assessment of cotton line MON88701 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 cotton line MON88701 is considered to be as safe for human consumption as food derived from conventional cotton cultivars.

A decision has been made to approve the draft variation to Standard 1.5.2 to include food derived from herbicide-tolerant cotton line MON88701 in the Schedule.

## **2. Introduction**

### **2.1 The Applicant**

Monsanto Australia Limited is a subsidiary of Monsanto Company, a multinational seed and technology provider to the agricultural sector and food industries.

### **2.2 The Application**

Application A1080 was submitted on 21 January 2013. The Application seeks approval for food derived from genetically modified (GM) cotton line MON88701 under Standard 1.5.2 – Food produced using Gene Technology.

Cotton line MON88701 is tolerant to two broad spectrum herbicides, dicamba and glufosinate ammonium through the introduction of the *dmo* gene from *Stenotrophomonas maltophilia* and the *bar* gene from *Streptomyces hygroscopicus*. These genes from soil bacteria encode the DMO and PAT proteins respectively. Neither DMO nor PAT protein is new to the food supply. Expression of the PAT protein has been used in many previously assessed GM foods to confer tolerance to glufosinate ammonium. The DMO protein has previously been assessed by FSANZ in Application A1063 which related to dicamba tolerant soybean line MON87708, which was approved on 26 March 2012.

### **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 on 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.

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 or novel protein from an approved GM variety 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 on a case-by-case basis.

### **2.4 Reasons for accepting the Application**

The Application was accepted for assessment because:

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

### **2.5 Procedure for assessment**

The Application was assessed under the General Procedure.

## **2.6 Decision**

The draft variation to Standard 1.5.2, as proposed following assessment, was approved without change.

The approved variation to the Standard is at Attachment A.

An Explanatory Statement is at Attachment B.

## **3. Summary of the assessment**

### **3.1 Risk assessment**

A detailed description of the process used by FSANZ for the safety assessment of GM foods is available on the FSANZ website at

[http://www.foodstandards.gov.au/consumer/gmfood/safety/documents/GM%20FINAL%20Sept%2007L%202 .pdf](http://www.foodstandards.gov.au/consumer/gmfood/safety/documents/GM%20FINAL%20Sept%2007L%202.pdf)

The safety assessment of cotton line MON88701 is provided in the supporting document (SD1) and included the following key elements:

- a characterisation of the transferred genes, their origin, function and stability in the cotton 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 MON88701 cotton 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 were identified. On the basis of the scientific data provided in the present Application, and other available information, food derived from cotton line MON88701 is as safe for human consumption as food derived from conventional cotton cultivars.

### **3.2 Risk management**

#### **3.2.1 Labelling**

In accordance with the labelling provisions in Standard 1.5.2, food derived from cotton line MON88701 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein, or has altered characteristics. The safety assessment has determined that food derived from cotton line MON88701 does not have altered characteristics.

The main food product from cotton plants is refined cottonseed oil. Extensive processing of cottonseed to produce food-grade oil 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 cottonseed oil from MON88701 would be exempt from labelling under paragraph 4(1)(c) of Standard 1.5.2. More minor food products such as cotton linters are almost pure cellulose and therefore do not contain novel protein or novel DNA and would also be exempt from labelling.

### **3.2.2 Detection methodology**

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions has been formed by the Implementation Sub-Committee for Food Regulation to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM applications.

The EAG has indicated that for GM applications, the DNA sequence of the entire insert and some adjacent genomic DNA is sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR-based detection method. For cotton line MON88701, the sequence information was supplied by the Applicant to satisfy the requirement for detection methodology in the FSANZ Application Handbook (FSANZ, 2011).

### **3.2.3 Summary of submissions**

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions. Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified, review research material if appropriate, and prepare a response to those issues. While not all opinion and comments can be taken on board during the process, all are valued and make a contribution to the rigour of the assessment.

Public submissions were invited on a draft variation which was available for public comment between 19 July – 29 August 2013; six submissions were received. Of these, three submissions were opposed to the approval of cotton line MON88701 for a variety of reasons. The main issues of concern were related to the use of biotechnology in food production, the use of GM crops for animal feed, and the use of herbicides on food crops. Other issues included views about the dominance of multinational organisations in the agricultural sector, the impact of international trade agreements, and the need for sustainability in food production.

FSANZ can only address food safety issues in its assessment of GM foods; broader issues expressed in some submissions are outside FSANZ's regulatory authority. Environmental issues are considered in Australia by the Office of the Gene Technology Regulator, and in New Zealand by the Environmental Protection Authority. The appropriate and safe use of herbicides in food production is managed primarily in Australia by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

All issues raised in the submissions have been comprehensively discussed in previous assessment reports prepared by FSANZ. Scientific discussion in international forums over the last ten years has allowed regulatory scientists to reach well-informed consensus views on a number of topics of public concern, and has facilitated making decisions based on the best available evidence. The use of a comparative approach for the safety assessment of GM foods has been affirmed and reinforced in this ongoing process. No changes to the safety assessment (SD1) were necessary as a result of consideration of the issues raised in submissions. Minor changes in the wording of some sections have been included to improve clarity or context.

#### **3.2.3.1 General issues**

The main issues raised in submissions have been summarised and responses are provided in Table 1.

**Table 1: Summary of general issues raised in submissions**

Issue	Submission	FSANZ Response
<b>Concern with the safety of all GM food, including the assessment process</b>	<ul style="list-style-type: none"> <li>Physicians &amp; Scientists for Global Responsibility</li> <li>Hugh Halliday</li> <li>Claire McFee</li> </ul>	<p>The approach used by FSANZ to assess the safety of GM food is based on core principles developed almost 20 years ago and published as guidelines by the Codex Alimentarius Commission (Codex, 2003; Codex, 2004). Over time, the assessment protocol has been the subject of scientific scrutiny, however it has proved to be a robust approach for whole food safety assessments. It is widely adopted and implemented around the world. While philosophical opposition to the technology remains, consumers can be confident that GM foods assessed under the protocol and approved for food use are as safe as their conventional counterparts.</p> <p>Studies cited as evidence of safety concerns with certain GM foods have been examined by FSANZ and other scientific experts around the world. The studies have been subject to significant scientific criticism and generally are not supported. Responses to several recent publications are available on the FSANZ website (<a href="http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx">http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx</a>).</p>
<b>The ingestion of transgenic DNA</b>	<ul style="list-style-type: none"> <li>Physicians &amp; Scientists for Global Responsibility</li> </ul>	<p>The ingestion of genes (DNA) from plants, animals and microbes is a normal part of the human diet. Genes that have been transferred from one organism to another (transgenes) are not different from the genes normally in foods and in many cases originate from plants already in the diet. Transgenes are referred to as 'novel DNA' for the simple purpose of identifying them from the repertoire of endogenous genes already in a crop plant.</p> <p>There is no 'dosage effect' from consuming DNA from any food source including GM plants, as it is digested in a normal way regardless of the source. Similarly, there can be no cumulative effects from consuming transgenic DNA; it behaves as any other nucleic acid present in the diet and forms part of the nutrient base of foods.</p>
<b>Safety of food from animals fed GM crops</b>	<ul style="list-style-type: none"> <li>Claire McFee</li> </ul>	<p>Scientific evidence published by organisations such as the OECD, and regulatory assessment agencies such as EFSA indicates that feeding GM plant material to animals does not affect the nutritional value or safety of food products (meat, milk, eggs etc) derived from those animals.</p> <p>A complete response is available on the FSANZ website at:  <a href="http://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx">http://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx</a></p>

Issue	Submission	FSANZ Response
<p><b>General concern with the spraying of herbicides on food crops</b></p>	<ul style="list-style-type: none"> <li>Physicians &amp; Scientists for Global Responsibility</li> <li>Claire McFee</li> </ul>	<p>The appropriate use of herbicides on all food crops grown in Australia is thoroughly evaluated by the APVMA. Where necessary following toxicological evaluation, a maximum residue limit (MRL) is determined for the use of a specific herbicide on a crop. The MRL is entered into the Schedule in Standard 1.4.2 Maximum Residue Limits in the Code, and applies to the listed food commodity, regardless of whether it is a conventional or GM crop.</p> <p>While the use of a particular herbicide on a tolerant crop typically results in a different pattern of usage of that herbicide compared with conventional crops, it does not necessarily result in any significant change in residues. See discussion on herbicide residues in Section 4.6 of SD1.</p>
<p><b>Whole food animal feeding studies to address questions about long-term toxicity; Testing GM foods in the same way that pharmaceuticals are tested.</b></p>	<ul style="list-style-type: none"> <li>Physicians &amp; Scientists for Global Responsibility</li> <li>Claire McFee</li> </ul>	<p>Many experts in toxicology consider that animal feeding studies with GM foods are difficult to design with adequate scientific integrity and, because of concerns about the unethical use of animals, cannot be justified.</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. 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. In these limited cases, the altered nutritional profile of the food may lend itself to investigation in animal diets, or in human volunteers. However, the majority of GM crops with agronomic traits have the same nutritional profile as conventional foods.</p> <p>Recent publications (Seralini <i>et al</i>, Carman <i>et al</i>) have claimed to show evidence of harm in animals fed GM food. However, assessment of these studies by FSANZ and others indicates these claims are not supported by the data presented by the researchers. FSANZ has published a scientific appraisal of these studies to highlight their deficiencies as tools for assessment, see <a href="http://www.foodstandards.gov.au/consumer/gmfood/Pages/Response-to-Dr-Carman's-study.aspx">http://www.foodstandards.gov.au/consumer/gmfood/Pages/Response-to-Dr-Carman's-study.aspx</a> ; <a href="http://www.foodstandards.gov.au/consumer/gmfood/seralini/Pages/default.aspx">http://www.foodstandards.gov.au/consumer/gmfood/seralini/Pages/default.aspx</a></p>
<p><b>Increase in food allergies in New Zealand and other developed countries may be due to ingestion of GM foods; food intolerance.</b></p>	<ul style="list-style-type: none"> <li>Physicians &amp; Scientists for Global Responsibility</li> <li>Claire McFee</li> </ul>	<p>While this is often cited as a concern by submitters, clinical allergy experts and those involved in the study of allergy generally do not regard this as a serious hypothesis.</p> <p>The increased prevalence of allergies in people eating Western diets is attributed to major allergens already in the food supply – milk, eggs and tree nuts, particularly peanuts (Mullins, 2007). 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 GM crops.</p> <p>The evaluation of newly expressed proteins for potential allergenicity is an integral part of the safety assessment of any GM food. This procedure is designed to identify and screen out any newly expressed protein that is found to raise an allergy concern.</p>



### **3.2.3.2 Issue relating to MON88701 cotton**

*Separate acute oral toxicity studies in mice using the respective E. coli-produced test substances DMO and PAT were submitted by the Applicant, but were not included in the safety assessment. Such studies are highly relevant to anyone concerned about the findings and should have been included for others to assess independently (Claire McFee).*

Response: Supporting studies, including any acute oral toxicity studies in animals, for GM food applications are publicly available from the FSANZ website.

Both DMO and PAT proteins were assessed for potential allergenicity and toxicity (See Section 4 in SD1) according to the FSANZ safety assessment guidelines (FSANZ, 2007). This approach is consistent with the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (Codex, 2003).

Where the biochemical, bioinformatics, digestibility and stability studies indicate further investigation of potential toxicity is warranted, the acute oral toxicity studies would have been necessary. However, the suite of laboratory and *in silico* analyses conducted on the DMO and PAT proteins for this assessment, in addition to similar studies conducted for previous assessments, provided conclusive evidence of no potential toxicity for either protein. Importantly, the digestibility studies indicated that these proteins would not survive digestion in the human gastrointestinal tract, if they were to be consumed. Therefore, the acute oral studies in animals, in this case, provide no additional scientific information for the purposes of GM food safety assessment. Moreover, as the foods derived from MON88701 cotton are refined vegetable oil and cottonseed linters (pure carbohydrate), it would be reasonable to conclude no dietary exposure to either of the newly expressed proteins.

## **3.3 Risk communication**

FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media portals and the publication, Food Standards News. Subscribers and interested parties were also notified.

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.

Documents relating to Application A1080, including submissions received from the public, are available on the FSANZ website.

## **4. Reasons for decision**

The variation to the Code to permit the sale and use of food derived from herbicide-tolerant cotton line MON88701 in Australia and New Zealand was approved based on available evidence, for the following reasons:

- The safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce cotton line MON88701.
- Food derived from cotton line MON88701 is equivalent to that derived from the conventional counterpart and other commercially available cotton cultivars in terms of its safety for human consumption and nutritional adequacy.

- Labelling of food derived from cotton line MON88701 will be required in the ingredients list or in conjunction with the name of the food, if it contains novel DNA or novel protein.
- There were no measures that would be more cost-effective than a variation to Standard 1.5.2 and could achieve the same end.

## 4.1 Section 29

FSANZ had regard to the following matters under 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 outweighed the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- whether other measures (available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Application
- any relevant New Zealand standards
- any other relevant matters.

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

### 4.1.1 Cost/benefit analysis

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 points below list the effect that approving the draft would be expected to have on various sectors.

**Consumers:** Broader availability of imported food products as there would be no restriction on any foods containing cotton line MON88701.

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

Labelling of products in accordance with the provisions in the Standard would allow consumers wishing to avoid certain GM cotton products to do so.

**Government:** Benefit that if cotton line MON88701 was detected in imported foods, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of cotton line MON88701 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 cottonseed oil or derivatives from MON88701 would benefit as they 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 imported foods containing cottonseed products.

Possible cost to food industry as some food ingredients derived from cotton line MON88701 might be required to be labelled.

As food from cotton line MON88701 has been found to be as safe as food from conventional cotton cultivars, not preparing a draft variation would offer little benefit to consumers, as approval of cotton line MON88701 by other countries could limit the availability of certain imported food products in the Australian and New Zealand markets. In addition, this option would result in the requirement for segregation of any products containing cotton line MON88701 from those containing approved cotton lines, which would be likely to increase the costs of certain imported foods.

Also, not preparing 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.

#### **4.1.2 Other measures**

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

#### **4.1.3 Relevant New Zealand standards**

Standard 1.5.2 applies in New Zealand.

#### **4.1.4 Any other relevant matters**

The Applicant has submitted an application seeking regulatory approval for MON88701 cotton in other countries, as listed in Table 1. To date, the product has been approved by the US Food and Drug Administration (FDA) where the process has been completed.

The Applicant has indicated that submissions will be made to countries that are significant importers of cotton, or food and feed products from countries where MON88701 cotton will be grown, and where established regulatory review processes are in place. This will result in submissions to a number of additional government regulatory agencies including the Ministry of Agriculture, People's Republic of China.

**Table 1: List of countries to whom applications for regulatory approval of MON88701 cotton have been submitted**

Country	Agency	Request
USA	Animal and Plant Health Inspection Service (APHIS), Department of Agriculture (USDA)	Determination of Nonregulated Status for MON88701, and progenies derived from crosses with other cotton lines.
	Food and Drug Administration (USFDA)	Food and feed safety and nutritional assessment.
Canada	Canadian Food Inspection Agency (CFIA)	Environment and animal feed
	Health Canada (HC)	Food approval
Japan	Ministry of Health, Labor, and Welfare (MHLW)	Food use
	Ministry of Agriculture, Forestry and Fisheries (MAFF)	Environment and feed
Korea	Ministry of Food and Drug Safety (Formerly Korea Food and Drug Administration)	Food approval
	Rural Development Administration (RDA)	Feed approval
Mexico	Ministry of Health	Food use
Europe	European Food Safety Authority (EFSA)	Food use

It is the Applicant's intention that cotton line MON88701 will be commercially cultivated in major production areas in North America and in Australia, but not in New Zealand. Cultivation in Australia would require a separate, independent assessment by the Office of the Gene Technology Regulator (OGTR), including an assessment of any environmental impact, before commercial release could be permitted.

## **4.2 Addressing FSANZ's objectives for standards setting**

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

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

Food derived from cotton line MON88701 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 cotton line MON88701 is considered as safe as food derived from other commercial cotton cultivars.

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

In accordance with existing labelling provisions, food derived from cotton line MON88701 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see Section 3.2.1).

### 4.2.3 The prevention of misleading or deceptive conduct

The requirement for detection methodology (see Section 3.2.2) addresses this objective.

### 4.2.4 Subsection 18(2) considerations

FSANZ has also had regard to the objectives set out 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 all GM foods applies broad concepts and principles outlined in the Codex General Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2004). Based on these principles, the risk analysis undertaken for cotton line MON88701 used the best scientific evidence available.

The Applicants submitted to FSANZ, a comprehensive dossier of quality-assured raw experimental data in line with Application Handbook requirements. 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. Cotton line MON88701 is a new food crop designed to provide growers in a number of countries, including Australia, with an alternative weed management strategy.

- *The promotion of fair trading in food*

The cost/benefit analysis in Section 4.1 lists a number of considerations that address fair trading with respect to cotton line MON88701.

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

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

## 4.3 Implementation

The variation will take effect on gazettal.

## 5. References

Codex (2003) *Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants*. Report No. CAC/GL 45-2003, Codex Alimentarius.  
[http://www.codexalimentarius.net/web/standard\\_list.do?lang=en](http://www.codexalimentarius.net/web/standard_list.do?lang=en).

Codex (2004) *Principles for the risk analysis of foods derived from modern biotechnology*. Report No. CAC/GL 44-2003, Codex Alimentarius Commission, Rome.  
[http://www.codexalimentarius.net/web/standard\\_list.do?lang=en](http://www.codexalimentarius.net/web/standard_list.do?lang=en).

FSANZ (2007) *Safety assessment of genetically modified foods – Guidance document*. Document prepared by Food Standards Australia New Zealand.  
[http://www.foodstandards.gov.au/srcfiles/GM%20FINAL%20Sept%2007L%20\\_2\\_.pdf](http://www.foodstandards.gov.au/srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf).

FSANZ (2011) *Application handbook*. Prepared by Food Standards Australia New Zealand.  
<http://www.foodstandards.gov.au/foodstandards/changingthecode/applicationshandbook.cfm>.

Mullins, R.J. (2007). Paediatric food allergy trends in a community-based specialist allergy practice, 1995-2006. *Medical J. Australia* 186(12), 618-621.

OECD (1993) *Safety evaluation of foods derived by modern biotechnology: Concepts and principles*. Organisation for Economic Co-operation and development, Paris.

## **Attachments**

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

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



### **Food Standards (Application A1080 – Food derived from Herbicide-tolerant Cotton MON88701) 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 [To be completed by Standards Management Officer]

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

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

**1 Name**

This instrument is the *Food Standards (Application A1080 - Food derived from Herbicide-tolerant Cotton MON88701) Variation*

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

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

**3 Commencement**

This variation commences on the date of gazettal.

**SCHEDULE**

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

“

	3.13	Food derived from herbicide-tolerant cotton line MON88701	
--	------	---	--

”



## **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.

FSANZ accepted Application A1080 which seeks permission for the sale and use of food derived from herbicide-tolerant cotton line MON88701. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to Standard 1.5.2.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation<sup>2</sup>, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the 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 and operation**

As it is not listed in the Schedule to Standard 1.5.2, food derived from cotton line MON88701 is not currently permitted for sale or use in food. This variation permits the sale, or use in food, of food derived from cotton line MON88701.

### **3. Documents incorporated by reference**

This 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 A1080 included one round of public consultation following an assessment and the preparation of a draft variation to the Standard and associated report. Submissions were called for on 19 July 2013 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Standard 1.5.2 is likely to have a minor impact on business and individuals.

---

<sup>2</sup> Previously known as the Australia and New Zealand Food Regulation Ministerial Council

**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 cotton line MON88701 into the Schedule to Standard 1.5.2.