



**FOOD STANDARDS**  
Australia New Zealand  
Te Mana Kounga Kai – Ahitereiria me Aotearoa

**15 July 2009**  
**[11-09]**

## **FIRST REVIEW REPORT**

### **APPLICATION A615**

### **FOOD DERIVED FROM INSECT-PROTECTED COTTON LINE COT67B**

For information on matters relating to this Assessment Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/> \

# CONTENTS

1.	INTRODUCTION .....	3
2.	OBJECTIVES OF REVIEW .....	3
3.	GROUNDS FOR THE FIRST REVIEW .....	3
3.1	<i>Protection of public health and safety</i> .....	3
4.	BACKGROUND .....	4
5.	CONCLUSIONS FROM THE FINAL ASSESSMENT REPORT .....	4
6.	ISSUES ADDRESSED IN FIRST REVIEW .....	4
6.1	<i>Ingestion of recombinant DNA in food</i> .....	4
6.2	<i>Purity of samples used for compositional analyses</i> .....	5
6.3	<i>Previous reviews</i> .....	5
7.	REVIEW OPTIONS .....	5
8.	DECISION .....	6
9.	IMPLEMENTATION AND REVIEW .....	6
	ATTACHMENT 1 - DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> .....	7
	ATTACHMENT 2 - EXECUTIVE SUMMARY AND REASONS FOR DECISION FROM THE FINAL ASSESSMENT REPORT .....	8
	ATTACHMENT 3 - LIST OF REFERENCES ON THE SAFETY OF RECOMBINANT DNA IN FOOD .....	11

## **1. Introduction**

On 9 February 2009, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested a First Review of Application A615, which seeks approval of food derived from a genetically modified (GM) cotton – namely, insect-protected cotton line COT67B. Approval of this Application involves a variation to Standard 1.5.2 – Food produced using Gene Technology, of the *Australia New Zealand Food Standards Code* (the Code).

Following a request for a formal review, FSANZ sought an extension to complete a response, which was accepted. In this instance, FSANZ was required to review the decision by 31 August 2009.

## **2. Objectives of Review**

The objective of this Review is to reconsider the draft variation to Standard 1.5.2 in light of the Ministerial Council's grounds for review as outlined in Section 3 below.

## **3. Grounds for the First Review**

A First Review of FSANZ's decision to approve Application A615 was sought on the grounds that the proposed amendment to Standard 1.5.2, to permit the sale and use of food derived from insect-protected cotton line COT67B, does not protect public health and safety.

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

In asserting that the decision to approve food derived from cotton line COT67B does not protect public health and safety, two issues are raised in the First Review request.

Firstly, FSANZ is asked to clarify what is known about any potential health implications of work establishing proof of principle for persistence and uptake of foreign DNA in and across the gastrointestinal (GI) tract of mammals. The rationale for requesting a First Review of food derived from insect-protected cotton line COT67B on these grounds is identical to that used for the First Review of Applications A592 (glyphosate-tolerant soybean line MON89788), A595 (insect-protected corn line MON 89034), A589 (glufosinate ammonium-tolerant rice line LLRICE62) and A1001 (insect-protected corn line MIR162). It has been suggested that the First Review Report for these Applications did not provide that clarity, although FSANZ has noted that the Ministerial Council did not request a Second Review of any of these applications.

Secondly, clarification is requested as to whether glyphosate-tolerant cotton line GHB614 and control samples used in the compositional analysis were pure, as contamination of non-GM control samples with GM material would mask differences and reduce the confidence that can be placed in a conclusion of no significant difference. The concern arises as a previous safety assessment, for glyphosate-tolerant soybean MON 89788 (A592) acknowledged contamination of one of the non-GM control samples with GM material ( $\leq 3.05\%$ ). It is contended that such contamination may not be unusual and the Final Assessment Report for this Application provides no information about sampling and testing protocols.

On this basis, the Review request claims that a conclusion of compositional equivalence cannot be accepted. In summary, the Review request states that FSANZ should determine whether purity was adequately assessed, the outcome of that assessment, and if contamination occurred, clarify the policy it applies when evaluating compositional analysis results and cross-contamination, including whether a contamination tolerance has been set. The First Review request for this Application claims that ‘this matter was not addressed adequately in the First Review Report for A1001, and so is raised again’.

## **4. Background**

FSANZ received an Application from Syngenta Seeds Pty Ltd (the Applicant) on 27 September 2007. The Applicant requested an amendment to Standard 1.5.2 to permit the sale and use of food derived from a new genetically modified variety of cotton, COT67B. Standard 1.5.2 prohibits a food produced using gene technology from being sold or used as an ingredient or component of any food unless it is listed in the Table to clause 2 of that Standard.

COT67B cotton has been genetically modified to be protected against feeding damage caused by the larvae of certain insect pest species. Protection is achieved through the expression in the plant of an insecticidal protein (a Cry protein) derived from *Bacillus thuringiensis*, a common soil bacterium.

Cotton line COT67B is intended to be grown in the United States, but may also be grown in Australia at a later date. Food from COT67B cotton is therefore expected to initially enter the Australia and New Zealand food supply via imported products. Approval is therefore necessary before these products may enter the Australian and New Zealand markets.

Prior to approval, FSANZ completed a comprehensive safety assessment of food derived from insect-protected cotton line COT67B. The assessment included consideration of (i) the genetic modification to the plant; (ii) the potential toxicity and allergenicity of the novel proteins; and (iii) the composition of COT67B cotton compared with that of conventional cotton varieties. No public health and safety concerns were identified as a result of the safety assessment

## **5. Conclusions from the Final Assessment Report**

The Executive Summary and the reasons for the decision, which were approved by the FSANZ Board in December 2008, are provided in this Report at **Attachment 2**. The Board agreed to the recommendation of the Final Assessment Report to approve food from cotton line COT67B in view of the findings of the safety assessment that food derived from this line is as safe and wholesome as food derived from other commercial cotton varieties.

## **6. Issues addressed in First Review**

### **6.1 Ingestion of recombinant DNA in food**

The persistence and uptake of ingested recombinant DNA in the GI tract is a general issue that has been the subject of extensive consideration and publication for more than 15 years.

Based on prolonged scientific discourse, the consensus view is that as DNA from all living organisms is structurally similar, the presence of recombinant DNA in food products, in itself, poses no additional health risk to consumers (WHO 1991, WHO 1993, Karenlampi 1996, Jonas *et al* 2001, Gaye & Gillespie 2005, Flachowsky *et al* 2007, EFSA 2007)<sup>1</sup>. Similar conclusions have been reached by expert consultations and intergovernmental bodies which have been convened specifically to address the safety of the presence of antibiotic resistance marker genes in foods (WHO 1993, Karenlampi 1996).

FSANZ continues to monitor the scientific literature for studies relevant to the safety assessment of GM foods and is fully cognisant of the literature dealing with this topic. FSANZ does not regard this as an issue that requires specific and explicit consideration for each GM food assessment. A response on this issue prepared for other reviews is available on FSANZ's website at:

<http://www.foodstandards.gov.au/newsroom/factsheets/factsheets2008/gmfoodssafetyofinges4072.cfm>

## **6.2 Purity of samples used for compositional analyses**

The First Review request seeks clarification as to whether the samples of GM and control cottonseed used for compositional analysis were sufficiently pure to ensure a valid comparison between the GM line and its comparator.

Information provided by the Applicant indicates that routine laboratory testing of each lot of harvested seeds (transgenic and non-transgenic) is carried out using polymerase chain reaction methods (Taqman PCR), which detects specific genetic elements characteristic of GM events. No adventitious presence of GM material was detected in the control samples at 95% confidence level.

The Applicant has therefore demonstrated that the compositional studies, including the determination of the purity of samples used in the analyses, were conducted in compliance with GLP and that appropriate techniques with sufficient sensitivity for detecting any cross-contamination were used to verify the tested material. On this basis, FSANZ is satisfied that the conclusions drawn from the studies are scientifically valid. In future assessments, FSANZ will include relevant information on the integrity of the test materials used in the compositional analyses to ensure that there are no grounds for general concerns about sample purity.

## **6.3 Previous reviews**

The First Review request for this Application claims that the issue of trace levels of contamination in samples used in the compositional analysis of glyphosate-tolerant soybean line MON89788 (Application A592) was not adequately clarified. FSANZ cannot re-open issues that have been previously addressed to the satisfaction of the Ministerial Council, and where the matter has subsequently been finalised.

## **7. Review Options**

Three options were considered within this Review:

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<sup>1</sup>Full citations are listed in **Attachment 3**.

1. re-affirm approval of the draft variation to Standard 1.5.2 as notified to the Council; or
2. re-affirm approval of the draft variation to Standard 1.5.2 subject to any amendments FSANZ considers necessary; or
3. withdraw approval of the draft variation to Standard 1.5.2 as notified to the Council.

## **8. Decision**

FSANZ has considered the issues raised by the Ministerial Council in the First Review of Application A615 – Food derived from insect-protected cotton line COT67B. On the basis of the outcomes of the review, Option 1 is the preferred option. FSANZ has decided to re-affirm its approval of the draft variation to Standard 1.5.2 to permit the sale of food derived from insect-protected cotton line COT67B, as detailed in **Attachment 1**.

### **Decision**

**FSANZ re-affirms its approval of the draft variation to Standard 1.5.2 to permit the sale and use of food derived from insect-protected cotton line COT67B.**

## **9. Implementation and review**

The draft variation to Standard 1.5.2 of the Code will come into effect on the date of gazettal.

### **Attachments**

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Executive Summary and Reasons for Decision from the Final Assessment Report
3. List of references on the safety of recombinant DNA in food

**Draft variation to the *Australia New Zealand Food Standards Code***

*Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act (2003) and are not subject to disallowance or sunseting.*

**To commence: on gazettal**

[1] *Standard 1.5.2 of the Australia New Zealand Food Standards Code is varied by inserting in the Table to clause 2 –*

Food derived from insect-protected cotton line COT67B	
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### **Executive Summary and Reasons for Decision from the Final Assessment Report**

#### **Executive Summary**

Food Standards Australia New Zealand (FSANZ) received a paid Application from Syngenta Seeds Pty Ltd (the Applicant) on 27 September 2007. The Applicant has requested an amendment to the *Australia New Zealand Food Standards Code* (the Code), specifically to Standard 1.5.2 – Food produced using Gene Technology, to permit the sale and use of food derived from a new genetically modified (GM) variety of cotton, COT67B. Standard 1.5.2 prohibits a food produced using gene technology from being sold or used as an ingredient or component of any food unless it is listed in the Table to clause 2 of that Standard.

COT67B cotton has been genetically modified to be protected against feeding damage caused by the larvae of certain insect pest species. Protection is achieved through the expression in the plant of an insecticidal protein derived from *Bacillus thuringiensis*, a common soil bacterium.

COT67B cotton is intended initially for cultivation in the United States of America but may also be grown in Australia at a later date. Food from COT67B cotton is therefore expected to initially enter the Australian and New Zealand food supply via imported products.

#### **Safety Assessment**

FSANZ has completed a comprehensive safety assessment of food derived from insect-protected cotton line COT67B. The assessment included consideration of (i) the genetic modification to the plant; (ii) the potential toxicity and allergenicity of the novel proteins; and (iii) the composition of COT67B cotton compared with that of conventional cotton varieties.

No public health and safety concerns were identified as a result of the safety assessment. On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from insect-protected cotton line COT67B is considered as safe and wholesome as food derived from other commercial cotton varieties.

#### **Labelling**

If approved, food derived from insect-protected cotton line COT67B will be required to be labelled as genetically modified if novel DNA and/or novel protein is present in the final food. Studies undertaken by the Applicant indicate detectable levels of novel protein in linters and cottonseed meal, but not in refined cottonseed oil.

Labelling addresses the requirement of section 18(1)(b) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act): provision of adequate information relating to food to enable consumers to make informed choices.



## **Impact of regulatory options**

Two regulatory options were considered in the assessment: (1) no approval, or (2) approval of food derived from insect-protected cotton line COT67B based on the conclusions of the safety assessment.

Following analysis of the potential costs and benefits of each option on affected parties (consumers, the food industry and government), approval of this application is the preferred option as the potential benefits to all sectors outweigh the costs associated with the approval.

## **Purpose**

The Applicant seeks amendment to Standard 1.5.2, to include food derived from insect-protected cotton line COT67B in the Table to clause 2.

## **Decision**

**Amend Standard 1.5.2 – Food produced using Gene Technology, to include food derived from insect-protected cotton line COT67B in the Table to clause 2.**

## **Reasons for Decision**

An amendment to the Code approving food derived from insect-protected cotton line COT67B in Australia and New Zealand is approved on the basis of the available scientific 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 insect-protected cotton line COT67B;
- food derived from insect-protected cotton line COT67B is equivalent to food from the conventional counterpart and other commercially available cotton varieties in terms of its safety for human consumption and nutritional adequacy;
- labelling of certain food commodities derived from insect-protected cotton line COT67B will be required if novel DNA and/or protein is present in the final food; and
- a regulation impact assessment process has been undertaken that also fulfils the requirement in New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is option 2, an amendment to the Code.

## **Consultation**

The Initial Assessment was advertised for public comment between 12 December 2007 and 6 February 2008; eleven submissions being received. The Draft Assessment was advertised for public comment between 6 August 2008 and 17 September 2008; eighty-two submissions were received. A summary of these is provided in **Attachment 3** to this Report. The majority of second round submissions were campaign notices calling for process-labelling of all GM foods.

FSANZ has taken submitters' comments into account in preparing the Final Assessment Report. Specific issues relating to insect-protected cotton line COT67B have been addressed in the Report.

### List of references on the safety of recombinant DNA in food

#### References considered in previous reviews

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