

**10-05**  
**7 December 2005**

## **FIRST REVIEW REPORT**

### **APPLICATION A533**

### **FOOD DERIVED FROM GLUFOSINATE – AMMONIUM TOLERANT COTTON LINE LL25**

## 1. Introduction

On 17 November 2005, the Australia and New Zealand Food Regulation Ministerial Council requested a First Review of Application A533, which seeks approval of Food Derived from Glufosinate-Ammonium Cotton Line LL25. Approval of this Application involves a variation to Standard 1.5.2 – Food Produced by Gene Technology, of the *Australia New Zealand Food Standards Code* (the Code).

Following a request for a formal review, FSANZ has 3 months to prepare a response, in this instance, FSANZ is required to review the decision by 17 February 2006.

## 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 concerns as outlined in Section 3.

## 3. Grounds for the review requested by the Ministerial Council

The First Review was requested on the grounds that Application A533 'does not protect public health and safety' and 'does not provide adequate information to enable informed choice'. No specific reasons were given.

## 4. Issues addressed in First Review

The issues raised by the Ministerial Council in this First Review have been addressed by the measures adopted at Final Assessment, which were re-affirmed at First Review, these are summarised in the following table:

<b>Ministerial Council issue</b>	<b>Measures taken at Final Assessment</b>	<b>Additional measures at First Review</b>
<ul style="list-style-type: none"><li>• Protection of public health and safety</li></ul>	<ul style="list-style-type: none"><li>• FSANZ carried out a full safety assessment and is satisfied that Glufosinate-Ammonium Tolerant Cotton Line LL25 is safe for human consumption, and is not a public health and safety concern.</li><li>• As for all GM applications, FSANZ called for two rounds of public comments; there were no specific concerns with the public health and safety of cotton line LL25.</li></ul>	FSANZ reviewed the safety assessment report of Food Derived from Glufosinate-Ammonium Tolerant Cotton Line LL25 and concluded that all the criteria outlined in FSANZ's Guidelines for GM food Applications had been satisfied and no further data was required.

Ministerial Council issue	Measures taken at Final Assessment	Additional measures at First Review
<ul style="list-style-type: none"> <li>Inadequate information</li> </ul>	<ul style="list-style-type: none"> <li>Labelling of GM foods provides information to enable informed choice. Under the labelling regulations of GM foods in Standard 1.5.2, if novel DNA and/or protein were found in the final food then labelling would be required. However, no novel DNA was present in food (refined oil and linters) derived from Glufosinate-Ammonium Tolerant Cotton Line LL25, and it is highly unlikely that protein would be present in this food. Therefore, labelling would not be required.</li> </ul>	<p>FSANZ re-affirms that labelling is not required on food derived from a GM crop that does not contain novel DNA and/or protein.</p>

## 5. Review Options

There are three options proposed for consideration under this Review:

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

No additional data has been presented to the Board to justify consideration of Options 2 and 3.

The recommended option is Option 1.

## 6. The Decision

FSANZ reaffirms the approval of the draft variation to Standard 1.5.2 of the Code which permits the use and sale of Food Derived from Glufosinate-Ammonium Tolerant Cotton Line LL25.

The proposed draft variation is provided in **Attachment 1**.

## Attachments

1. Draft variation to the *Australia New Zealand Food Standards Code*.
2. Summary and Conclusions from the Final Assessment Report

## ATTACHMENT 1

### DRAFT VARIATION TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

**To commence: on gazettal**

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

Food derived from glufosinate ammonium tolerant cotton line LL25
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### SUMMARY AND CONCLUSIONS FROM THE FINAL ASSESSMENT REPORT

#### Background

Food derived from genetically modified (GM) cotton line LL25 has been assessed for its safety for human consumption. This cotton line has been genetically modified to be tolerant to the herbicide glufosinate ammonium and has been developed principally for cultivation in the United States and Canada. The line in this application is known commercially as LibertyLink® cotton.

A number of criteria have been addressed in the safety assessment including: a characterisation of the transferred genes, their origin, function and stability; changes at the DNA, protein and whole food levels; compositional analyses; evaluation of intended and unintended changes; and the potential for the newly expressed proteins to be either allergenic or toxic to humans.

#### History of Use

Cotton is grown primarily for the value of its fibre with cottonseed and its processed products being a by-product of the crop. Humans have consumed cottonseed oil, the major product of cottonseed, for decades. Cottonseed oil is considered to be premium quality oil, valued for its high-unsaturated fatty acid content. The other food use of cottonseed is the linters, which are composed of greater than 99% cellulose. Cottonseed itself and the meal fraction are not presently used in Australia and New Zealand as a food for human consumption because they contain naturally occurring toxic substances. These toxins are essentially removed in the production of oil and linters, making them fit for human consumption. The types of food products likely to contain cottonseed oil are frying oils, mayonnaise, salad dressing, shortening, and margarine. After processing (NCPA, 1990), linters may be used as high fibre dietary products and thickeners in ice cream and salad dressings.

#### Description of the Genetic Modification

Cotton line LL25 was generated through the transfer of the *bar* gene to the non-transgenic cotton line Coker 312. The *bar* gene encodes the protein phosphinothricin acetyltransferase (PAT), an enzyme that confers tolerance to glufosinate ammonium (phosphinothricin). The *bar* gene is derived from the soil bacterium *S. hygroscopius*.

No functional antibiotic resistance genes were transferred to cotton LL25. Detailed molecular and genetic analyses of cotton line LL25 indicate that the transferred *bar* gene is stably integrated into the plant genome at a single insertion site and is stably inherited from one generation to the next.

## **Characterisation of Novel Protein**

Cotton line LL25 express a single novel protein – PAT. Protein expression analyses indicate that PAT is expressed at low levels or is undetectable in the cotton and their processed fractions and therefore exposure to the protein through consumption of food derived from cotton line LL25 would be negligible, if at all.

In cotton line LL25, PAT was present at levels ranging from 48 to 75 µg/g fresh weight (equivalent to 0.019% to 0.036% of the total crude protein) in fuzzy seed and from 0.13 to 1.4 µg/g fresh weight (equivalent to 0.001% to 0.006% of the total crude protein) in lint. Levels of PAT were much lower in the cotton hulls and meal and were undetectable in crude or deodorised oil, the main cottonseed products used in the human food supply.

The safety of PAT has been assessed on numerous previous occasions by FSANZ. In all instances it has been concluded that PAT is non-toxic to humans and has limited potential as a food allergen.

## **Compositional Analyses**

Compositional analyses were done to establish the nutritional adequacy of cotton line LL25, and to compare it to non-transformed control lines and commercial varieties of cotton. The constituents measured were protein, fat, carbohydrate, ash, moisture, fibre, fatty acids, amino acids, minerals and the anti-nutrients, gossypol, cyclopropenoid acids and phytic acid, trypsin inhibitor, lectins, isoflavones, raffinose and stachyose.

No differences of biological significance were observed between the cotton line LL25 and its non-GM counterparts. Several minor differences in key nutrients and other constituents were noted however the levels observed represented very small percentage changes and do not indicate an overall pattern of change that would warrant further investigation. On the whole, it was concluded that food from cotton line LL25 is equivalent in composition to that from other commercial cotton varieties.

## **Nutritional Impact**

The detailed compositional studies are considered adequate to establish the nutritional adequacy of the food and indicate that food derived from cotton line LL25 is equivalent in composition to food from non-GM cotton varieties. The introduction of food produced from cotton line LL25 into the food supply is therefore expected to have minimal nutritional impact. The nutritional adequacy of food produced from cotton line LL25 was also confirmed using a feeding study in rapidly growing broiler chicks. This demonstrated that the cottonseed meal from cotton line LL25 is equivalent to that from non-GM cotton in its ability to support typical growth and wellbeing.

## **Conclusion**

No potential public health and safety concerns have been identified in the assessment of food from cotton line LL25. On the basis of the data provided in the present application, and other available information, food from this cotton line can be considered as safe and as wholesome as food produced from other cotton varieties.