

9-04

15 December 2004

FIRST REVIEW REPORT

APPLICATION A509

FOOD DERIVED FROM INSECT-PROTECTED COTTON LINE COT102

1. Objectives of Review

The Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) has requested a First Review of a draft variation to Standard 1.5.2 – Food Produced by Gene Technology, of the *Australia New Zealand Food Standards Code* (the Code). FSANZ is required to review the decision by 27 December 2004.

Application A509 – Food derived from insect protected cotton line COT102 seeks to have Standard 1.5.2 amended to include food derived from insect protected cotton line COT102.

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 2.

2. Review on grounds requested by the Ministerial Council

The First Review was requested on the grounds that Application A509 'does not protect public health and safety' and 'does not provide adequate information to enable informed choice'. The specific reason given was that 'inadequate research has been carried out to determine unintended modification that may occur in the refined product'.

Following a request for a formal Review, FSANZ has three months to complete the Review. In this particular case, the Review is required to be completed by 27 December 2004.

The Board sought further information from the Council in order to ensure that its review of Application A509 adequately addressed the basis on which the Council made its request. The Chair of the FSANZ Board, the Hon Rob Knowles, requested this information from the Hon Tony Abbott, Minister for Health and Ageing as the Chair of Ministerial Council, in order to facilitate the review. Members of the Ministerial Council indicated that there was no further information that could be provided in relation to the basis for the review request.

3. Background

An Application has been received from Syngenta to amend the Code to approve food derived from a genetically modified (GM) insect-protected cotton, cotton line COT102. Standard 1.5.2 – Food Produced using Gene Technology – requires that GM foods undergo a pre-market safety assessment before they may be sold in Australia and New Zealand.

Cotton line COT102 has been genetically modified for protection against cotton bollworm (*Helicoverpa armigera*) and native budworm (*H. punctigera*) two significant pests of cotton crops in Australia. Protection is conferred by the expression in the plant of a bacterially derived protein toxin (a *Bt*-toxin) that is specific for these two insects. Cotton line COT102 also contains a gene encoding resistance to the antibiotic hygromycin.

4. Conclusions from the Final Assessment Report

4.1 Safety assessment

FSANZ has completed a comprehensive safety assessment of food derived from cotton line COT102. The assessment included consideration of: (i) the genetic modification to the plant; (ii) the safety of any transferred antibiotic resistance genes; (iii) the potential toxicity and allergenicity of any new proteins; and (iv) the composition and nutritional adequacy of the food, including whether there had been any unintended changes.

No potential public health and safety concerns were identified in the assessment of food derived from cotton line COT102. Therefore, on the basis of all the available evidence, including detailed studies provided by the applicant, it has been concluded that food derived from cotton line COT102 is as safe and wholesome as food derived from other cotton varieties.

4.2 Labelling

Food from cotton line COT102 will require labelling if novel DNA and/or protein (refer to Standard 1.5.2 for the definition of novel DNA/protein) are present in the final food. The only food products derived from cotton are cottonseed oil and linters, neither of which contain DNA or protein. Therefore, food products containing cottonseed oil or linters derived from cotton line COT102 will not be required to be labelled as containing GM ingredients. Labelling addresses the requirement of section 10 (1)(b) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), namely, provision of adequate information relating to food to enable consumers to make informed choices.

4.3 Impact of regulatory options

Two regulatory options were considered in the assessment: either (1) no approval; or (2) approval of food from cotton line COT102 based on the conclusions of the safety assessment. Following an assessment of the potential impact of each of the options on the affected parties (consumers, the food industry and government), option 2 is the preferred option as it potentially offers significant benefits to all sectors with very little associated cost. The proposed amendment to the Code, giving approval to food from cotton line COT102, is therefore considered of net benefit to both food producers and consumers.

4.4 Consultation

FSANZ undertook two rounds of public consultation in relation to this Application. In response, three submissions were received during the first round, and four submissions were received in the second round. Two of the first-round submitters expressed support for the application, contingent on a satisfactory safety assessment, and the remaining submitter informed FSANZ that it would comment once the Draft Assessment Report was available. After the second round of consultation, one of the submissions supported the application. The other three expressed no opinion either way. Other specific comments made in the submissions are discussed in section 5.3.

As this Application involves a novel gene and protein that FSANZ has not assessed before, comments on the safety assessment were sought from two external reviewers. In general, the reviewers agreed with the conclusions of the safety assessment of COT102. Specific comments have been addressed in the safety assessment report or in this report.

4.5 Statement of Reason

An amendment to the Code to give approval to the sale and use of food derived from cotton line COT102 in Australia and New Zealand without any special conditions, was agreed by FSANZ in July 2004 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 cotton line COT102;
- food derived from cotton line COT102 is equivalent to food from other commercially available cotton varieties in terms of its safety for human consumption and nutritional adequacy;
- 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 amendment to the Code is of net benefit to both food producers and consumers;
- the proposed draft amendment to the Code is consistent with the section 10 objectives of the FSANZ Act and the regulatory impact assessment.

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

5. Review Options

There are three options proposed for consideration under this Review:

1. reaffirm approval of the draft variation to Standard 1.5.2 of the Code as notified to the Council; or
2. reaffirm 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 a consideration under option 2 and 3.

The recommended option is Option 1.

6. Conclusion

FSANZ reaffirms its approval of the draft variation to Standard 1.5.2 of the Code.

Attachment

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

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 –*

[1.1] *inserting in Column 1 of the Table to clause 2 -*

Oil and linters derived from insect-protected cotton line COT102	
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