

1-05
9 February 2005

FIRST REVIEW REPORT

APPLICATION A518

FOOD DERIVED FROM INSECT-PROTECTED, HERBICIDE-TOLERANT COTTON LINE MXB-13

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 using Gene Technology, of the *Australia New Zealand Food Standards Code* (the Code). FSANZ is required to review the decision by 10 March 2005.

Application A518 – Food derived from Insect-Protected, Herbicide-tolerant Cotton Line MXB-13 seeks to have Standard 1.5.2 amended to include food derived from insect protected herbicide tolerant cotton line MXB-13.

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. Grounds for the review requested by the Ministerial Council

The First Review was requested on the grounds that Application A518 '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'. With regard to this point, the food products derived from cotton line MXB-13 (cottonseed oil and linters) are highly refined and therefore contain no novel DNA or protein, and are identical in composition to oil and linters derived from conventional cotton varieties.

3. Background

An Application has been received from Dow AgroSciences to amend the Code to approve food derived from a genetically modified (GM) insect-protected cotton, cotton line MXB-13. 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 MXB-13 contains two insecticidal genes (*cry1Ac* and *cry1F*), derived from the common soil bacterium *Bacillus thuringiensis* (*Bt*). These genes express insecticidal proteins (*Cry1Ac* and *Cry1F*) that are toxic to specific lepidopteran caterpillar insects, including the major pests of cotton. The insecticidal genes were introduced separately into two cotton lines (MXB-7 and MXB-9) and these two traits were subsequently combined by crossing the two GM cotton lines to produce cotton line MXB-13.

In addition, cotton line MXB-13 contains two copies of a selectable marker gene (*pat*) from the bacterium *Streptomyces viridochromogenes*, which produces an enzyme, phosphinothricin acetyltransferase (PAT), that detoxifies the herbicide glufosinate ammonium. PAT functions as a selectable marker in the initial laboratory stages of plant cell selection and thus cotton line MXB-13 is also tolerant to the herbicide glufosinate ammonium.

4. Conclusions from the Final Assessment Report

4.1 Safety assessment

FSANZ has completed a comprehensive safety assessment of food derived from cotton line MXB-13 as required under the *Food Standards Australia New Zealand Act 1999* (the FSANZ Act). 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 MXB-13. Therefore, on the basis of all the available evidence, including detailed studies provided by the Applicant, it has been concluded that food, namely oil and linters, derived from cotton line MXB-13 is as safe and wholesome as food derived from other cotton varieties.

4.2 Labelling

Food derived from cotton line MXB-13 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 MXB-13 will not be required to be labelled as containing GM ingredients.

Labelling addresses the requirement of section 10(1)(b) of the FSANZ Act; 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 oil and linters derived from cotton line MXB-13 based on the conclusions of the safety assessment. Following cost and benefit analysis 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 MXB-13, 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, five submissions were received during the first round, and four submissions were received in the second round. Following the first round of consultation, none of the submitters objected to the approval of food derived from cotton line MXB-13, however, one reserved comment until the release of the Draft Assessment Report. After the second round of consultation, all four submitters supported the approval of food derived from cotton line MXB-13.

4.5 Statement of Reasons

An amendment to the Code to give approval to the sale and use of food, namely oil and linters, derived from cotton line MXB-13 in Australia and New Zealand is agreed 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 MXB-13;
- food derived from cotton line MXB-13 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; and
- the proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act. In particular, it ensures the protection of public health and safety, and is based upon risk analysis using the best available scientific evidence.

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 Ministerial 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 Ministerial 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. 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 inserting into Column 1 of the Table to clause 2 –*

Oil and linters derived from insect-protected, glufosinate ammonium-tolerant cotton line MXB-13
