



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

12 December 2007
[8-07]

INITIAL ASSESSMENT REPORT

APPLICATION A614

FOOD DERIVED FROM GLYPHOSATE-TOLERANT COTTON LINE GHB614

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 6 February 2008
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

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

Executive Summary

An Application has been received from Bayer CropScience to amend the *Australia New Zealand Food Standards Code* (the Code) to approve food derived from genetically modified (GM) cotton, line GHB614. 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.

The purpose of this Initial Assessment Report is to provide relevant information, supplied by the Applicant, to assist in identifying the affected parties and to outline the relevant issues necessary to complete assessment of the Application.

Bayer CropScience has developed the cotton line GHB614, expressing a modified corn EPSPS protein, which confers tolerance to the herbicide glyphosate.

Cotton line GHB614 has been developed for cultivation in major cotton producing countries worldwide, including eventually in Australia. Cotton derivatives, such as oil and linters may enter the Australian and New Zealand food chain via locally produced and imported cotton by-products.

This Initial Assessment Report is not an assessment of the merits of the Application but rather is an assessment of whether the Application should be accepted for further consideration, according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Reasons for Assessment

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for food derived from glyphosate-tolerant cotton line GHB614. If accepted, the approval would warrant a variation to Standard 1.5.2.
- There is currently no permission in the Code for food derived from cotton line GHB614.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same end.
- At this stage no other relevant matters are apparent.

Consultation

Public submissions are now invited on this Initial Assessment Report. Comments are specifically requested on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from cotton line GHB614.

Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should state this in your submission and clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 6 February 2008.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing standards.management@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

INTRODUCTION

An Application was received from Bayer CropScience on 27 September 2007 seeking approval for food derived from glyphosate-tolerant cotton, line GHB614 (also known as GlyTol™), under Standard 1.5.2 – Food produced using Gene Technology.

The genetic modification in cotton line GHB614 consists of a single trait introduced by the transfer of the following gene:

- the *2mepsps* gene, encoding the enzyme 5-enol-pyruvylshikimate-3-phosphate synthase (2mEPSPS). The wild type *2mepsps* gene was originally isolated from corn and two point mutations were introduced using site-directed mutagenesis. The EPSPS protein is a key enzyme in the shikimate pathway which links the metabolism of carbohydrates to the biosynthesis of ring-containing compounds, including aromatic amino acids. The wild type corn EPSPS protein is sensitive to glyphosate inhibition. The mutations introduced to 2mEPSPS reduce its sensitivity to glyphosate while retaining its function in the shikimate pathway.

An Initial Assessment of the Application has been completed and public comment is now being sought to assist in the Draft Assessment of the Application.

The Draft Assessment will include a full safety assessment of food (oil and linters) derived from cotton line GHB614 to assess its safety for human consumption.

1. Background

1.1 Current standard

Standard 1.5.2 requires that a genetically modified (GM) food undergo a pre-market safety assessment before it may be sold in Australia and New Zealand. Foods that have been assessed under the Standard, if approved, are listed in the Table to clause 2 of the Standard.

1.2 Regulatory status in other countries

Bayer CropScience has initiated a consultation with United States Food and Drug Administration and filed a Pre-market Biotechnology Notification (PBN).

A Petition for the Determination of Nonregulated Status for Cotton line GHB614 has also been submitted to the United States Department of Agriculture.

2. The Issue / Problem

Bayer CropScience has developed glyphosate-tolerant cotton line GHB614 for cultivation in major cotton producing countries worldwide.

Glyphosate (N-phosphonomethylglycine) is a non-selective, broad spectrum herbicide. The mode of action of glyphosate is to specifically bind to, and block, the activity of native plant EPSPS. The glyphosate tolerance of cotton line GHB614 is conferred by the introduction of a modified *epsps* gene; the *2mepsps* gene.

The 2mEPSPS enzyme produced in the cotton line GHB614 is insensitive to glyphosate inhibition, but retains its normal functions in the shikimate pathway.

Before food derived from cotton line GHB614 can enter the food supply in Australia and New Zealand, it must first be assessed for safety and an amendment to the Code must be approved by the FSANZ Board, and the decision subsequently notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). An amendment to the Code may only be gazetted, once the Ministerial Council process has been finalised.

Bayer CropScience has therefore applied to have Standard 1.5.2 amended to include food derived from cotton line GHB614.

3. Objectives

The objective of this assessment is to determine whether it would be appropriate to amend the Code to approve the use of food derived from cotton line GHB614 under Standard 1.5.2. In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives, which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Questions for consideration in the risk assessment

Based on information provided by the Applicant on the nature of the genetic modification, the molecular characterisation, the characterisation of the novel protein, the compositional analysis and any nutritional issues, is food derived from cotton line GHB614 as safe as that derived from conventional varieties of cotton?

Is there other available information, including from the scientific literature, general technical information, independent scientists, other regulatory agencies and international bodies, and the general community that needs to be considered?

Are there any other considerations that would influence the outcome of this assessment?

RISK ASSESSMENT

5. Risk Assessment

Food derived from cotton line GHB614 will be evaluated according to the safety assessment guidelines prepared by FSANZ¹. The safety assessment will include the following:

- a characterisation of the genetic modification to the plant;
- characterisation of any novel proteins, including their potential toxicity and allergenicity; and
- a comparative analysis of the key constituents of cotton line GHB614.

The Applicant has submitted a large data package in support of their application and has provided studies on the molecular characterisation of the inserted DNA, the toxicity and potential allergenicity of the novel proteins, and compositional analyses of processed commodities derived from cotton line GHB614, as well as animal feeding studies. In addition to information supplied by the Applicant, FSANZ will also have regard to other available information, including from the scientific literature, general technical information, independent scientists, other regulatory agencies and international bodies, and the general community.

RISK MANAGEMENT

6. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand.

There are no options other than a variation to the Code for this Application. Therefore the two regulatory options available for this Application are:

6.1 Option 1: Prohibit food derived from cotton line GHB614

Maintain the *status quo* by not amending Standard 1.5.2 to approve the sale and use of food (oil and linters) derived cotton line GHB614.

6.2 Option 2: Approve food derived from cotton line GHB614

Amend Standard 1.5.2 of the Code to permit the sale and use of food (oil and linters) derived from cotton line GHB614, with or without listing special conditions in the Table to clause 2 of Standard 1.5.2.

¹ FSANZ (2007) Guidance Document – Safety Assessment of Genetically Modified Foods

7. Impact Analysis

7.1 Affected Parties

The affected parties to this Application include the following:

- consumers, particularly those who have concerns about biotechnology;
- food importers and distributors of wholesale ingredients;
- the manufacturing and retail sectors of the food industry; and
- Government generally, where a regulatory decision may impact on trade; and enforcement agencies including who will need to ensure that any approved products are correctly labelled.

Before cotton line GHB614 can be cultivated in Australia, it will need to be assessed for its potential impacts on the environment by the Office of Gene Technology Regulator (OGTR). It can only be grown in Australia if it is approved by OGTR.

7.2 Benefit Cost Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

To develop the analysis of the costs and benefits of the regulatory options proposed, FSANZ seeks comment on the following:

- What are the potential costs or benefits of this application to you as a stakeholder? Do the benefits outweigh the costs?
- What are the costs or benefits for consumers in relation to public health and safety, consumer information and labelling, etc?
- What are the costs or benefits for business – compliance, reporting, costs, savings, increased market opportunities both domestically and overseas?
- What are the costs or benefits for government – administration, enforcement, public health and safety, etc?

COMMUNICATION

8. Communication and Consultation Strategy

This Application is for approval of a food under an existing standard. As a result, FSANZ has applied a basic communication strategy to Application A614. This involves advertising the availability of assessment reports for public comment in the national press and making the reports available on the FSANZ website. FSANZ will issue a media release drawing journalists' attention to the matter.

The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the Application. If approval is recommended, once the FSANZ Board has approved the Final Assessment Report, FSANZ will notify the Ministerial Council. The Applicant and Stakeholders, including the public, will be notified of the gazettal of changes to the Code in the national press and on the website.

FSANZ provides an advisory service to the jurisdictions on changes to the Code.

9. Consultation

9.1 Public consultation

Public comment is sought on the Initial Assessment Report for this Application.

The purpose of the Initial Assessment Report is to seek early input on: a range of specific issues known to be of interest to various stakeholders; the likely regulatory impact; and stakeholders' views on any matter of interest to them in relation to the Application.

All stakeholders that make a submission in relation to the Application will be included on a mailing list to receive further FSANZ documents in relation to the application. If readers of this Initial Assessment Report are aware of others who might have an interest in this Application, they should bring this to their attention. Other interested parties, as they come to the attention of FSANZ, will also be added to the mailing list for public consultation.

At this stage FSANZ is seeking public comment to assist it in assessing this Application. All stakeholders must observe the relevant due date for submissions.

Comments that would be useful could cover:

- Scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from cotton line GHB614;
- Parties that might be affected by having this Application approved or rejected;
- Arguments in support of or opposition to permitting food from amylase-modified cotton line GHB614; and
- Potential costs and benefits to consumers, industry and government.

9.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

Guidelines for assessing the safety of GM foods have been developed by the Codex Alimentarius Commission and have the status of standards for WTO purposes. An amendment to the Code to allow food derived from cotton line GHB614 may be of interest to other WTO member nations because it pertains to the safety of GM food and is likely to have a liberalising effect on international trade. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

10. Conclusion and Reasons for Assessment

This Initial Assessment Report is based mainly on information provided by the Applicant and discusses relevant issues in relation to approving food derived from cotton line GHB614. After having regard to the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for food (oil and linters) derived from cotton line GHB614. Such an approval, if accepted, would warrant a variation to Standard 1.5.2.
- There is currently no permission in the Code for food derived from cotton line GHB614.
- The Application is not so similar to any previous application that it ought not be accepted.
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