



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

8-06

13 December 2006

INITIAL ASSESSMENT REPORT

APPLICATION A589

FOOD DERIVED FROM GLUFOSINATE AMMONIUM-TOLERANT RICE LLRICE62

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 7 February 2007

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 Pty Ltd seeking to amend the *Australia New Zealand Food Standards Code* (the Code) to approve food derived from a genetically modified (GM) variety of rice, line LLRICE 62, under Standard 1.5.2 – Food produced using Gene Technology. This Standard requires that GM foods undergo a pre-market safety assessment before they may be sold in Australia and New Zealand.

LLRICE 62 is tolerant to the herbicide glufosinate ammonium through the addition of a bacterial gene (*bar*). Expression of the *bar* gene produces an enzyme, phosphinothricin acetyl transferase (PAT), which inactivates the herbicide in the plants.

Purpose

Rice line LLRICE 62 is intended to be grown in overseas countries. Once the grain is commercialised however, rice products imported to Australia and New Zealand could contain derivatives of LLRICE 62. Approval is therefore required before these products could enter the Australian and New Zealand markets.

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 an evaluation of the Application.

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 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 derived from glufosinate ammonium-tolerant rice LLRICE 62. 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 LLRICE 62.
- 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 from LLRICE 62.

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 10 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 clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 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) 7 February 2007.

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 slo@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

1. Background

An Application was received from Bayer CropScience Pty Ltd on 6 September 2006 seeking approval in the Code for food derived from glufosinate ammonium-tolerant rice, known as LLRICE 62, under Standard 1.5.2 – Food produced using Gene Technology.

LLRICE 62 is a genetically modified (GM) variety of rice that is tolerant to the herbicide glufosinate ammonium by the addition of a bacterial gene, known as *bar*, to the rice genome. This gene encodes the enzyme phosphinothricin acetyltransferase (PAT), which inactivates the herbicide. The purpose of the modification is to provide growers with a line of rice that more effectively allows for weed control without affecting the crop.

LLRICE 62 has been developed primarily for cultivation in overseas countries where the herbicide will be registered for use on tolerant crops. It has already been approved for food use in the USA (2000), Canada (2006), Argentina (2006) and the Russian Federation (2003).

An Initial Assessment of the Application has been completed and public comment is now sought to assist in the preparation of the Draft Assessment of the Application. The Draft Assessment will include a full scientific evaluation of LLRICE 62 according to guidelines, to assess its safety for human consumption.

1.1 Previous consideration

The use of the *bar* gene from *Streptomyces hygroscopicus* for conferring herbicide tolerance in plants has been considered by FSANZ on previous occasions. Varieties of GM cotton and canola containing the *bar* gene have been assessed and are approved under Standard 1.5.2.

2. The Issue / Problem

Standard 1.5.2 requires that a 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.

The Applicant has developed LLRICE 62, a variety of GM rice tolerant to the herbicide glufosinate ammonium. Although commercial release of the grain will be in overseas countries, there is a possibility that any imported product that contains rice derivatives could include rice tolerant to glufosinate ammonium. The Applicant is therefore seeking an amendment to Standard 1.5.2 to include food derived from LLRICE 62 in Australian and New Zealand markets.

Food derived from LLRICE 62 must be assessed for safety before it can be permitted for food use in Australia and New Zealand. An amendment to the Code must be approved by the FSANZ Board, and subsequently be 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.

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 LLRICE 62 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 10 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. Key Assessment Questions

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, key questions in this assessment include:

- Is food derived from LLRICE 62 as safe as that derived from conventional varieties of rice?
- Is other information available, 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 other considerations that would influence the outcome of this assessment?

RISK ASSESSMENT

5. Risk Assessment Summary

Food from LLRICE 62 will be evaluated according to the safety assessment guidelines prepared by FSANZ¹. The assessment includes evaluation of the following information:

- the nature of the genetic modification including a full molecular characterisation of the gene/s inserted into the plant;
- protein characterisation of any novel proteins expressed in the plant, including their potential toxicity and allergenicity;
- analysis of the key constituents of rice line LLRICE 62 compared to conventional varieties.

The Applicant has submitted a comprehensive package of scientific data in support of their application, including relevant studies that will enable a Draft Assessment of this Application. In addition to information supplied by the Applicant, FSANZ will also consider other information, including from the scientific literature, general technical information, independent scientists, other regulatory agencies and international bodies, and the general community that is relevant to the safety assessment.

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 non-regulatory options for this Application. The two regulatory options available for this Application are:

6.1 Option 1 – Prohibit food from LLRICE 62

Maintain the *status quo* by not amending Standard 1.5.2 of the Code to approve food derived from glufosinate ammonium-tolerant rice line LLRICE 62.

6.2 Option 2 – Approve food from LLRICE 62

Amend Standard 1.5.2 of the Code to permit the sale and use of food derived from glufosinate ammonium-tolerant rice line LLRICE 62, with or without specified conditions in the Table to clause 2 of the Standard.

¹ FSANZ (2003) Information for Applicants – Format for applying to amend the Australian New Zealand Food Standards Code – Food Produced Using Gene Technology.

7. Impact Analysis

7.1 Affected Parties

The affected parties may 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 or WTO obligations, and enforcement agencies in particular who will need to ensure that any approved products are correctly labelled.

The cultivation of rice line LLRICE 62 in Australia or New Zealand could have an impact on the environment, which would need to be assessed by the Office of the Gene Technology Regulator (OGTR) in Australia, and by various New Zealand government agencies including the Environmental Risk Management Authority (ERMA) and the Ministry of Agriculture and Forestry (MAF) before cultivation in either of these countries could be permitted. LLRICE 62 has been developed primarily for cultivation overseas and, at this stage, the Applicant has no plans for cultivation in either Australia or New Zealand.

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 is a routine standards matter. As a result, FSANZ has applied a basic communication strategy to this Application that involves advertising the availability of assessment reports for public comment in the national press and placing the reports on the FSANZ website. In addition, FSANZ will issue a media release drawing journalists' attention to the matter.

The Applicant and individuals and organisations who 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, we 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. In addition, FSANZ provides an advisory service to the jurisdictions on changes to the Code.

9. Consultation

9.1 Public consultation

The purpose of the Initial Assessment Report is to seek input from the public on a range of specific issues considered to be of interest to various stakeholders, the likely regulatory impact at an early stage and any matter of interest in relation to this Application.

All stakeholders that make a submission on this Application will be included on a mailing list to receive further FSANZ documents relating to the Application. Other interested parties, as they come to the attention of FSANZ, will be added to the mailing list for public consultation.

At this stage, public comment is sought on the Initial Assessment Report to assist 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 from glufosinate ammonium-tolerant rice LLRICE 62;
- Parties that might be affected by the approval or rejection of this Application;
- Arguments supporting or opposed to the approval of food from glufosinate ammonium-tolerant rice LLRICE 62; 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 LLRICE 62 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

This Initial Assessment Report is based mainly on information provided by the Applicant and discusses relevant issues in relation to the evaluation of food derived from rice line

LLRICE 62. 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 derived from glufosinate ammonium-tolerant rice line LLRICE 62. Such an approval, if accepted, would warrant a variation to Standard 1.5.2 in the Code;
- There is currently no permission in the Code for food derived from LLRICE 62;
- 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; and
- At this stage no other relevant matters are apparent.

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.