



8-06
13 December 2006

INITIAL ASSESSMENT REPORT

APPLICATION A592

FOOD DERIVED FROM GLYPHOSATE-TOLERANT SOYBEAN MON 89788

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 Monsanto Australia Ltd to amend the *Australia New Zealand Food Standards Code* (the Code) to approve food derived from a genetically modified (GM) soybean, MON 89788. 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.

Soybean line MON 89788 has been genetically modified to be tolerant to the herbicide glyphosate. Tolerance is conferred by expression of the *cp4 epsps* gene in the soybean crop.

An earlier version of glyphosate-tolerant soybean, line 40-3-2, is already approved under Standard 1.5.2. Soybean line 40-3-2 currently accounts for 60% of the global production of soybean. The Applicant states that MON 89788 provides enhanced yield potential relative to their current product, 40-3-2. Australia and New Zealand import a considerable quantity of soybean and soybean products from the United States, a key market for production of MON 89788 soybeans. Therefore, it is likely that, if approved, imports of soybean and soybean products into Australia and New Zealand will contain MON 89788.

Major soybean products are soybean oil (used in margarines, cooking oils and salad dressings), soybean meal (mostly used in animal feed) and soybean protein products, including soybean flour (used widely in bakery products) and soybean protein isolates (used in various food products including simulated meats, soups, sauces, nutrition bars and protein-fortified drinks).

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).

Purpose

The Applicant seeks to amend Standard 1.5.2 - Food Produced using Gene Technology - to include food derived from glyphosate-tolerant soybean MON 89788 in the Table to clause 2.

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 soybean MON 89788. 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 soybean MON 89788.

- 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 soybean MON 89788.

Responses to this Initial Assessment Report will be used to develop the next stage of the Application and in 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

An Application was received from Monsanto Australia Limited on 19 October 2006 seeking approval for food derived from glyphosate-tolerant soybean (*Glycine max*) line MON 89788 under Standard 1.5.2 – Food produced using Gene Technology, in the Code.

The genetic modification involved the transfer of the *cp4 epsps* gene into soybean. This gene is from a common soil bacterium and encodes the protein CP4-EPSPS (5-enolpyruvyl-3-shikimate phosphate synthase), which confers tolerance to the herbicide glyphosate.

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 soybean MON 89788 to assess its safety for human consumption. If approved, imports of soybean and soybean food products into Australia and New Zealand are likely to contain MON 89788.

The Applicant made submissions for food and feed use to the US Food and Drug Administration and the USDA-Animal and Plant Health Inspection Service in mid-2006. Regulatory submissions for import approvals have been or will be made to countries that import significant soybean or soybean products, including China, Japan, Canada, Korea, the Philippines and Taiwan.

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.

2. The Issue / Problem

The Applicant has developed soybean plants that are tolerant to the herbicide glyphosate. These plants are referred to as soybean line MON 89788. The purpose of the modification is to provide growers with an effective method for controlling weeds, together with enhanced yield potential relative to their current herbicide tolerant product, soybean line 40-3-2. Food from soybean line 40-3-2 was approved in Australia and New Zealand in 2000. The Applicant states that soybean line MON 89788 has equivalent herbicide tolerance, and thus the same weed control benefits, as soybean line 40-3-2. However, soybean line MON 89788 is reported to have a yield advantage due to improvements in transformation technology that have allowed the gene cassette to be directly transformed into an elite soybean line, thus accelerating further breeding improvements.

Before food derived from soybean line MON 89788 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 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.

Monsanto Australia Limited has therefore applied to have Standard 1.5.2 amended to include food derived from soybean line MON 89788.

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 soybean line MON 89788 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, is food derived from soybean line MON 89788 as safe as that derived from conventional varieties of soybean?

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 Summary

Food from soybean line MON 89788 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;
- a comparative analysis of the key constituents of soybean line MON 89788.

The Applicant has submitted a comprehensive data package in support of their application and has provided studies on the molecular characterisation of the insert, the toxicity and potential allergenicity of the novel protein, and compositional analyses of grain (bean) and forage derived from soybean line MON 89788. 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 – *Status quo*

Maintain the *status quo* by not amending Standard 1.5.2 of the Code to approve the sale and use of food derived from glyphosate-tolerant soybean line MON 89788.

6.2 Option 2 - Approve food derived from soybean line MON 89788

Amend Standard 1.5.2 of the Code to permit the sale and use of food derived from glyphosate-tolerant soybean line MON 89788, with or without listing special conditions in the Table to clause 2 of Standard 1.5.2.

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

The cultivation of soybean line MON 89788 may have an impact on the environment, which would need to be assessed by the Office of the Gene Technology Regulator in Australia and by various New Zealand government agencies including the Environmental Risk Management Authority and the Ministry of Agriculture and Forestry before cultivation in either of these countries could be permitted. At this stage, the Applicant has no plans for cultivation in either country.

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 approval matter. As a result, FSANZ has applied a basic communication strategy to Application A592. This involves advertising the availability of assessment reports for public comment in the national press and making the reports available on the FSANZ website. We 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.

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, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders 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 from glyphosate-tolerant soybean line MON 89788;
- Parties that might be affected by having this application approved or rejected;
- Arguments in support of or opposition to permitting food from glyphosate-tolerant soybean line MON 89788; 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 soybean line MON 89788 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 approving food derived from soybean line MON 89788. 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 glyphosate-tolerant soybean line MON 89788. 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 soybean line MON 89788.
- The Application is not so similar to any previous application that it ought not be accepted.
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