

**1-05**  
**9 February 2005**

## **INITIAL ASSESSMENT REPORT**

### **APPLICATION A553**

## **FOOD DERIVED FROM GLYPHOSATE-TOLERANT COTTON LINE MON88913**

**DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 23 March 2005**  
**SUBMISSIONS RECEIVED AFTER THIS DEADLINE**  
**WILL NOT BE CONSIDERED**  
*(See 'Invitation for Public Submissions' for details)*

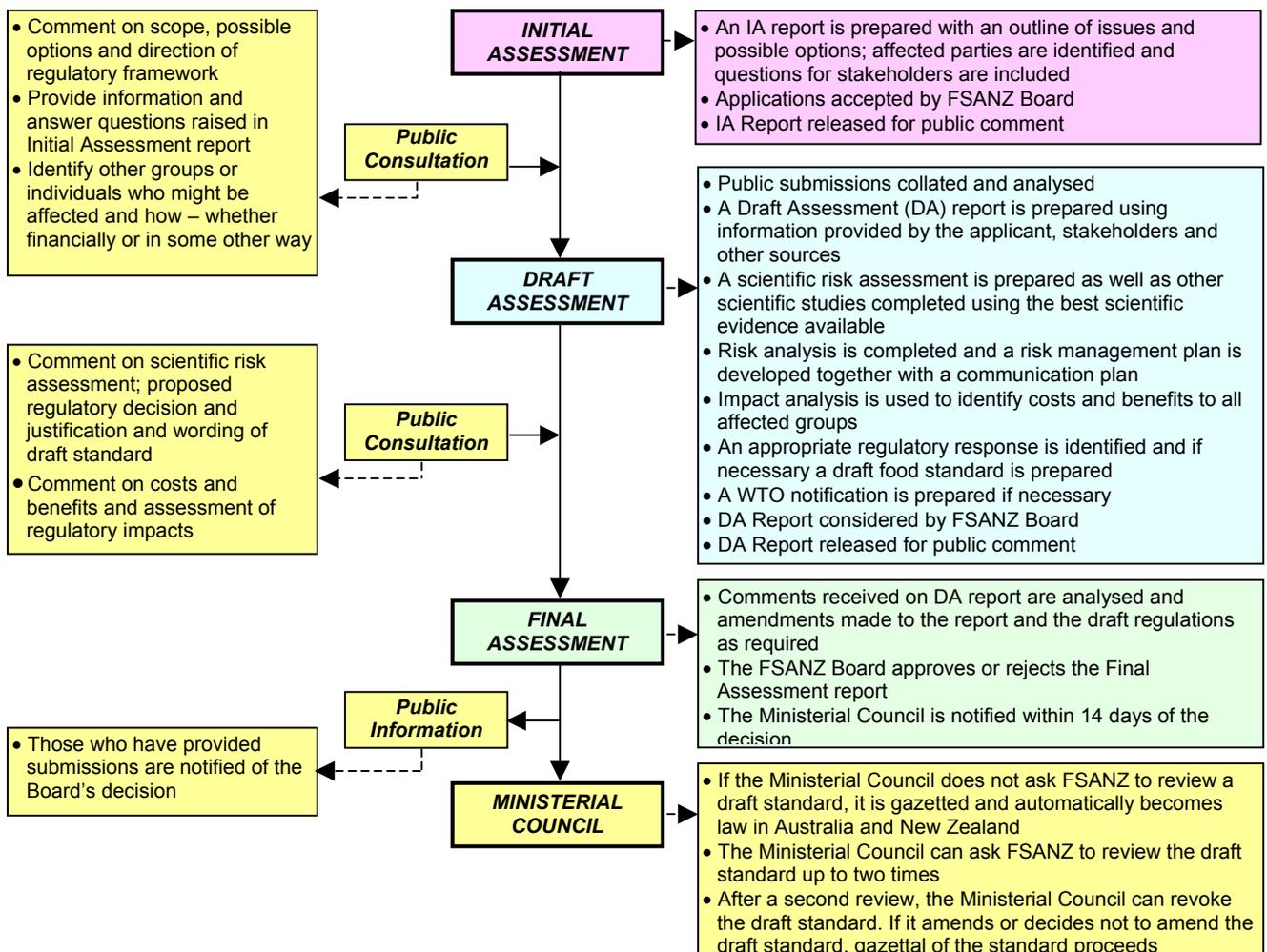
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ’s role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Australian Government; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Australian Government, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



## INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report for Application A553, which includes the identification and discussion of the key issues.

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 for 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](http://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](http://www.foodstandards.govt.nz)**

**Submissions need to be received by FSANZ by 6pm (Canberra time) 23 March 2005.**

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](mailto: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](mailto:info@foodstandards.gov.au).

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## **Executive Summary and Statement of Reasons**

An application has been received from Monsanto Australia Limited seeking to amend the *Australia New Zealand Food Standards Code* (the Code) to approve food derived from cotton line MON 88913, a variety that has been genetically modified (GM) for herbicide-tolerance. 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. The information needed to complete the assessment will include information received from public submissions.

The herbicide-tolerant trait introduced into cotton line MON 88913 is conferred by the addition of a bacterial gene encoding the EPSPS protein, a key enzyme in the biosynthesis of aromatic amino acids in both plants and microbes. The bacterial form of the EPSPS enzyme has a lower affinity for glyphosate, and so unlike the plant EPSPS, is able to function in the presence of glyphosate. Plants that are genetically modified to express the bacterial EPSPS protein are thus able to continue to grow in the presence of glyphosate.

To date, Roundup Ready<sup>®</sup> Flex cotton has been planted in contained field trials in Australia under the OGTR licence DIR 035/2003 since October 2003, and the applicant intends to release cotton line MON 88913 for commercial production in Australia. Roundup Ready<sup>®</sup> Flex cotton will not be grown in New Zealand, but food products derived from this cotton may enter New Zealand.

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).

### **Statement of Reasons**

This Application has been assessed against the requirements for Initial Assessment in section 13 of the FSANZ Act, and FSANZ has decided to accept this Application for the following reasons:

- the Application seeks approval for food derived from herbicide-tolerant cotton line 88913. An approval, if accepted, would warrant a variation to Standard 1.5.2;
- there is currently no permission for food derived from cotton line 88913;
- the Application is not so similar to any previous application that it ought not be accepted;
- at this stage of the assessment, there is no reason to believe that costs arising from a variation to include food derived from cotton line 88913 would outweigh the direct and indirect benefits to the community, government or industry that would arise from the variation; and
- there are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same objective.

Public submissions are now invited on this Initial Assessment Report. Comments are specifically requested on the scientific aspects of this Application, in particular, information that could be relevant to the safety assessment.

## 1. Introduction

An Application was received from Monsanto Australia Limited on 17 November 2004 seeking approval for food derived from glyphosate-tolerant cotton line 88913 (Roundup Ready® Flex cotton MON 88913) under Standard 1.5.2 - Food Produced Using Gene Technology, in the Code.

The genetic modification in cotton line MON 88913 consists of a single trait introduced by the transfer of the following gene derived from bacterial sources:

- the *cp4 epsps* gene which is the coding sequence for the native CP4 EPSPS protein, derived from *Agrobacterium* sp. strain CP4, an enzyme that 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.

## 2. Regulatory Problem

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.

The Applicant, Monsanto Australia Limited, has developed a new variety of herbicide-tolerant cotton, referred to as MON 88913, primarily for agronomic purposes. Before food derived from this cotton 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.

The Applicant therefore seeks amendment to Standard 1.5.2 to include food derived from cotton line 88913 in the Table to clause 2.

## 3. Objective

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.

The key objectives of this assessment of cotton line MON 88913 are therefore the protection of public health and safety and the provision of adequate information to consumers. In fulfilling these objectives, FSANZ will also have regard for the need for standards to be based on a risk analysis using the best available scientific evidence, and the benefits of an efficient and internationally competitive food industry.

## 4. Background

### 4.1.1 Purpose of the genetic modification

The Applicant has developed cotton plants that are genetically modified to be tolerant to the herbicide glyphosate. The particular cotton line that has been produced provides increased tolerance to glyphosate compared to previously developed glyphosate-tolerant cotton lines known generally as Roundup Ready<sup>®</sup> cotton. This improved tolerance has been achieved largely through the use of more efficient promoters that lead to improved expression over a longer growing period..

Cotton line 88913 has been developed by the insertion of the *cp4 epsps* gene, derived from the soil bacterium *Agrobacterium*. The modification did not involve the transfer of any antibiotic resistance genes. The purpose of the modification is to provide growers with an expanded window of application of the glyphosate herbicide and enhanced flexibility in weed control options, relative to the current Roundup Ready<sup>®</sup> cotton product.

Glyphosate is the active ingredient of the proprietary herbicide Roundup<sup>®</sup> which is used widely as a non-selective agent for controlling weeds in primary crops. The mode of action of glyphosate is to specifically bind to, and block, the activity of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), an essential enzyme involved in the biosynthesis of aromatic amino acids in all plants, bacteria and fungi. Glyphosate tolerance is conferred by the introduction of a bacterial gene (from *Agrobacterium* sp. strain CP4) which produces an EPSPS enzyme with a reduced affinity for glyphosate. The resultant level of enzyme activity is sufficient to produce the aromatic amino acids essential for growth and thus sustain the plant in the presence of the herbicide.

Cotton (*Gossypium hirsutum*) is the leading plant fibre crop produced in the world. It is grown commercially in over 88 countries with a combined production of 54 million metric tonnes of seed cotton and 18 million metric tonnes of cotton lint (AGBIOS Database 2001). Both cottonseed oil, and to a lesser extent cotton fibres, in the form of processed cotton linters, are routinely used for human food products. Cottonseed oil is a premium quality oil that may be used in a variety of foods including frying oil, mayonnaise, salad dressing, shortening, margarine and packing oil. Linters are short fibres removed from the cottonseed during processing (delinting). After extensive processing at alkaline pH and high temperatures, the linters may be used as high fibre dietary products, sausage casings and thickeners in ice cream and salad dressings. The linters consist primarily of cellulose (>99%).

#### 4.1.1 Previous assessments

A glyphosate-tolerant GM cotton expressing the CP4 EPSPS protein known as MON 1445, has already been assessed by FSANZ and was approved under Standard 1.5.2 for use in Australia and New Zealand in 2000 (Application A355). MON 1445 is also already approved in Argentina, Canada, China, Japan, the Philippines, South Africa and the U.S (AGBIOS Database 2001).

## 4.2 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 4 (level of complexity) and placed in Group 3 on the FSANZ standards development Work Plan. This Initial Assessment confirms these ratings. Further details about the Work Plan and its classification system are given in *Information for Applicants* at [www.foodstandards.gov.au](http://www.foodstandards.gov.au).

## 5. Relevant Issues

### 5.1 Safety assessment of food from cotton line MON 88913

Food from cotton line 88913 will be evaluated according to the safety assessment guidelines prepared by FSANZ<sup>1</sup>. The safety assessment will include the following:

- characterisation of the genetic modification to the plant
- characterisation of the novel protein, including its potential toxicity and allergenicity; and
- comparative analysis of the key constituents of cotton line 88913 with the conventional counterpart.

The Applicant has submitted a comprehensive scientific data package in support of their application. Studies on the molecular characterisation of the insert in cotton line MON 88913, the potential toxicity and potential allergenicity of CP4 EPSPS, and compositional analyses that focus on the food derived from cotton line MON 88913 have been provided. In addition to information supplied by the Applicant, the assessment will also entail the use of other available resource material including previous safety assessments, published scientific literature and general technical information. FSANZ will also have regard to independent scientists, other regulatory agencies and international bodies, and the general community.

### 5.2 Labelling

Under Standard 1.5.2, GM food must be labelled if novel DNA and/or protein is present in the final food and also where the food has altered characteristics.

The main food use of cotton is cottonseed oil, which would not be expected to contain DNA or protein because of the degree of processing. Cotton linters have a minor food use and also would not be expected to contain DNA or protein. Foods containing these ingredients would therefore not be required to be labelled.

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

## **6. Regulatory Options**

### **6.1 Option 1 – prohibit food from glyphosate-tolerant cotton line MON 88913**

Maintain the *status quo* by not amending the Code to approve the sale and use of food derived from glyphosate-tolerant cotton line 88913.

### **6.2 Option 2 – approve food from glyphosate-tolerant cotton line MON 88913**

Amend the Code to permit the sale and use of food derived from glyphosate-tolerant cotton line 88913, with or without listing special conditions of use in the Table to clause 2 of Standard 1.5.2.

## **7. Impact Analysis**

### **7.1 Affected parties**

- 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.

In the event that the Applicant proceeds to commercialise cotton line MON 88913 in the United States agricultural markets in the future, the approval of this application would ensure cotton or food imports from the US to Australia and New Zealand would comply with the Code.

### **7.2 Impact 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.

The following is an initial assessment by FSANZ of the costs and benefits of the two regulatory options identified so far. This is based on information supplied by the Applicant and experience FSANZ has gained from consideration of previous applications relating to GM foods. Your comments are also invited on the costs and benefits identified for the options below.

#### *7.2.1 Option 1*

Consumers: Cost in terms of a possible reduction in the availability of certain food products.  
Benefit to consumers if there are potential public health and safety issues.

Cost associated with higher retail prices for segregated foods.

No impact on consumers wishing to avoid GM foods, as food from cotton line 88913 is not currently permitted in the food supply.

Government: No immediate impact.

Potential impact if considered inconsistent with WTO obligations but impact would be in terms of trade policy rather than in government revenue.

Industry: Cost to animal growers as a possible reduction in the variety of animal feed products available. Cost to animal growers to source either segregated or non-GM feed.

Cost in terms of restricting innovation in food/crop production for both growers and other sectors of the food industry. Cost to the food industry to source either segregated or non-GM supplies.

Potential longer-term impact - any successful WTO challenge has the potential to impact adversely on food industry.

### 7.2.2 Option 2

Consumers: Possible benefit of lower prices, to the extent that savings from production efficiencies are passed on.

Benefit of access to a greater range of products including imported food products containing ingredients derived from cotton line 88913.

Cost to consumers wishing to avoid GM food by a potential restriction of choice of products, or increased prices for non-GM food.

Government: No direct impact.

Industry: Possible benefit to growers in lower production costs and reduced exposure to agricultural chemicals used to manage insect pests and weed species.

Benefit to importers and distributors of overseas food products as the product range is extended.

Benefit for food manufacturers in that the choice of raw ingredients is extended.

Benefit to food retailers in an increased product range.

**To further 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?**

## **8. Consultation**

### **8.1 Public comment**

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 in assessing this Application.

#### **Useful comments could cover:**

- **Scientific aspects of this application, in particular, information relevant to the safety assessment of food from cotton line 88913;**
- **Parties that might be affected by having this application approved or rejected;**
- **Arguments in support or opposition to permitting food from cotton line 88913; and**
- **Potential costs and benefits to consumers, industry and government.**

### **8.2 World Trade Organization (WTO)**

There are not any relevant international standards for this Application, and amending the Code to allow food derived from cotton line 88913 is unlikely to have a significant 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 and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (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.

## **9. Conclusion and Recommendation**

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 88913. After having regard to the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ accepts the application for the following reasons:

- the Application seeks approval for food derived from herbicide-tolerant cotton line 88913. 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 88913;
- the Application is not so similar to any previous application that it ought not be accepted;
- at this stage of the assessment, there is no reason to assume that costs arising from a variation to include food derived from cotton line 88913 would outweigh the direct and indirect benefits to the community, government or industry that would arise from the variation; and
- there are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same objective.

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