

9-04

15 December 2004

## **INITIAL ASSESSMENT REPORT**

### **APPLICATION A548**

## **FOOD DERIVED FROM CORN ROOTWORM & GLYPHOSATE-TOLERANT CORN MON 88017**

**DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 9 February 2005**

**SUBMISSIONS RECEIVED AFTER THIS DEADLINE**

**WILL NOT BE CONSIDERED**

*(See 'Invitation for Public Submissions' for details)*

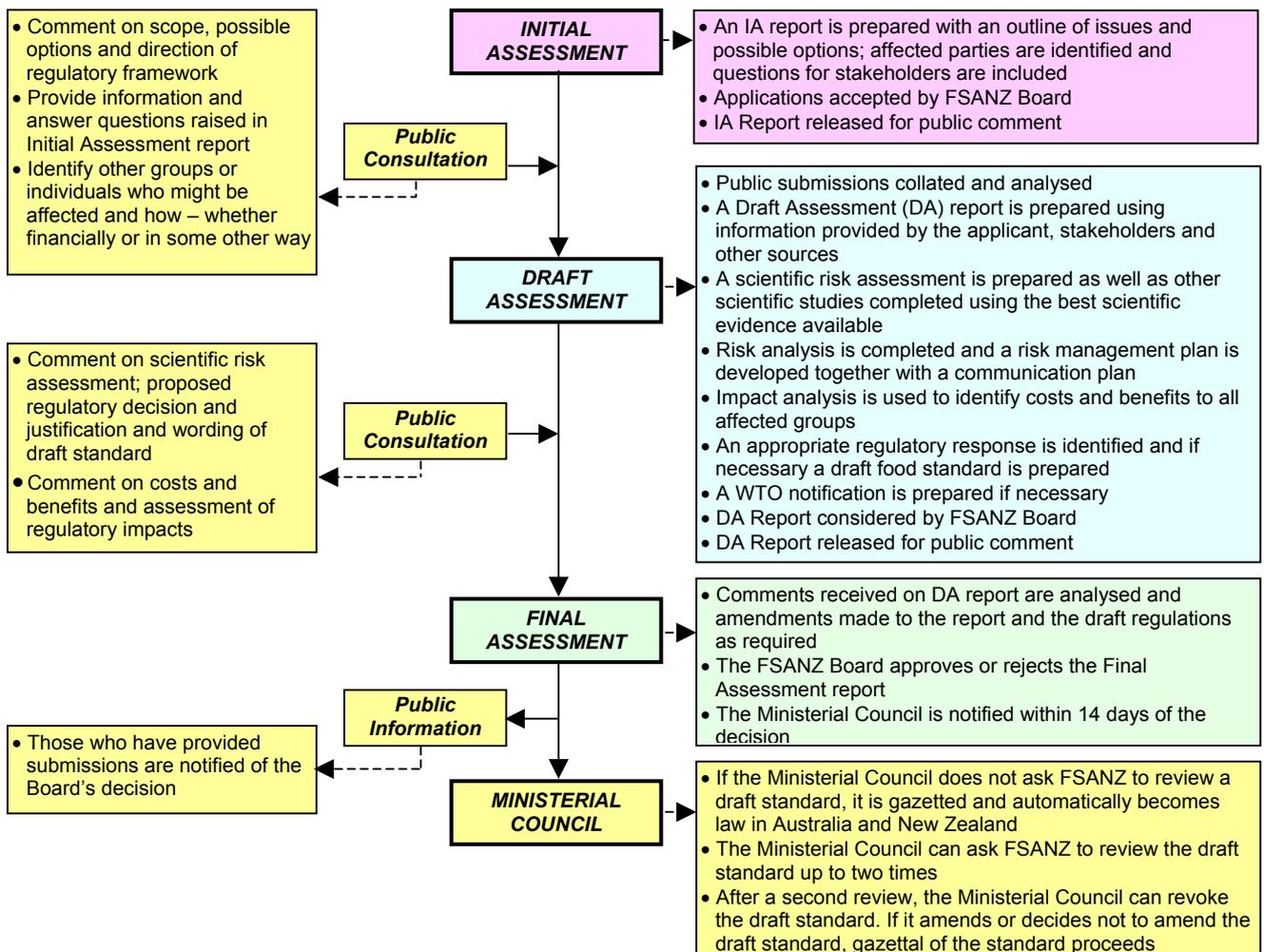
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 of Application A543, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment 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) 9 February 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 corn line 88017, a variety that has been genetically modified (GM) for insect-protection and 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 dual trait introduced into corn line 88017 involves the addition of two novel genes. One gene confers protection from corn rootworm, a significant insect pest of corn. Protection is conferred by the expression in the plant of a bacterially derived protein toxin (from the family of *Bt-δ* endotoxins) that is specific for the rootworm. The second gene confers tolerance to the herbicide glyphosate by the expression in the plant of an enzyme, CP4 EPSPS, also derived from a common soil bacterium.

Food ingredients derived from corn line 88017 could enter Australia and New Zealand as imports if the Applicant proceeds to commercialise this product in agricultural markets in the United States. There are currently no intentions to cultivate corn line 88017 in Australia or 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 insect-protected, herbicide-tolerant corn line 88017. An approval, if accepted, would warrant a variation to Standard 1.5.2;
- there is currently no permission for food derived from corn line 88017;
- 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 such a variation to include food derived from corn line 88017 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 5 October 2004 seeking approval for food derived from insect-protected, glyphosate-tolerant corn line 88017 (MON 88017) under Standard 1.5.2 - Food Produced Using Gene Technology, in the Code.

The genetic modification in MON 88017 is a dual trait introduced by the transfer of the following genes derived from bacterial sources:

- the synthetic *cry3Bb1* gene which is the coding sequence for a close variant of the Cry3Bb1 protein, derived from *Bacillus thuringiensis*, and one of the family of Cry3Bb proteins with specific insecticidal activity; and
- 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 insect-protected and herbicide-tolerant corn, referred to as MON 88017, primarily for agronomic purposes. Before food derived from this corn 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 New Zealand Food Regulation Ministerial Council (ANZFRMC). 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 corn line 88017 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 MON 88017 corn 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**

Corn plants are susceptible to damage from feeding by a Coleopteran insect pest, corn rootworm (*Diabrotica* spp.). The Applicant has previously developed two separate genetically modified (GM) inbred lines, one containing a trait that confers protection to the corn rootworm, and a second line that contains a trait that confers tolerance to the broad-spectrum herbicide glyphosate. These two inbred GM lines each containing the individual traits have previously been crossed using traditional plant breeding techniques to produce a corn hybrid with the dual trait. The traditional breeding process is considered inefficient, and requires long development times.

Corn line 88017 has therefore been developed using a two-gene insertion event that simultaneously creates corn rootworm-protection and glyphosate-tolerance in a single GM line. The purpose of the modification is to provide growers with access to a variety of elite corn germplasms containing both agronomic traits.

Corn line 88017 expresses a variant of the Cry3Bb1 protein isolated from the common soil bacterium *Bacillus thuringiensis* (*Bt*) subspecies *kumamotoensis*. This protein is toxic to specific insects, including three significant pests of corn: Western corn rootworm (*Diabrotica vigifera*), Northern corn rootworm (*Diabrotica berberis*) and Mexican corn rootworm (*Diabrotica vigifera zea*).

In addition, corn line 88017 expresses the enzyme 5-enolpyruvyl-3-shikimate phosphate synthase (EPSPS) from *Agrobacterium* sp. strain CP4. This enzyme, which is essential for aromatic amino acid synthesis, has a lower affinity for glyphosate compared to the plant version of EPSPS. The normal mode of action of the herbicide is to bind to the plant EPSPS, blocking the enzymic activity, which results in a lack of aromatic amino acids and leads to the death of plant cells. As glyphosate has a lower binding affinity for the bacterial form of the enzyme, expression of CP4 EPSPS in the plant cells allows continued production of aromatic amino acids in the presence of the herbicide.

Corn, together with rice and wheat, is one of the most important cereal crops in the world with total production of 591 million tonnes in 2000 (FAOSTAT Database 2001). The majority of grain and forage derived from maize is used in animal feed. Maize grain is also used for industrial products such as ethyl alcohol and highly refined starch. Domestic production of corn in Australia and New Zealand is supplemented by the import of a small amount of corn-based food ingredients, largely high-fructose corn syrup which is not currently manufactured in either Australia or New Zealand. Such products are processed into breakfast cereals, baking products, extruded confectionery and corn chips. Other food ingredients such as oils and cornstarch are also imported and used by the food industry for the manufacture of dessert mixes and canned foods.

An insect-protected GM corn expressing the Cry3Bb1 protein only, known as event MON 863, has already been assessed by FSANZ and was approved under Standard 1.5.2 for use in Australia and New Zealand in 2003 (Application A484). MON 863 is also already approved in Japan and the United States and has recently been assessed as safe for human consumption by the European Food Safety Authority (EFSA, 2004).

#### **4.1 Overseas regulatory status**

Applications to permit the use of corn varieties containing event MON 88017 have been submitted to multiple authorities in the United States (USDA, USFDA, EPA). In 2001, the EPA established a time-limited exemption from the requirements of a tolerance for *Bt* Cry 3Bb1 proteins and the genetic material necessary for its production in all commodities (EPA, 2001,a). An application to the EPA to amend the exemption by removing the time limitation was made in 2003. The EPA previously has reviewed and established an exemption from the requirement of a tolerance for CP4 EPSPS and the genetic material necessary for the production of this protein in or on all raw agricultural commodities.

An environmental approval from the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) for MON 88017 was obtained on April 23, 2003. The applicant states that regulatory submissions for import and production approvals will be made to countries that import US corn grain. These will include Japanese Ministry of Health, Labour and Welfare (MHLW) and MAFF (for use as animal feed), as well as the Canadian Food Inspection Agency (CFIA) and Health Canada. For countries that do not have a formal approval process, notifications of import will be made.

#### **4.2 Work Plan Classification**

This Application had been provisionally rated as Category of Assessment level 4 (degree 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 corn line 88017**

Food from corn line 88017 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 two novel proteins, including their potential toxicity and allergenicity; and
- comparative analysis of the key constituents of corn line 88017.

The Applicant has submitted a comprehensive scientific data package in support of their application. Studies on the molecular characterisation of the insert in MON 88017, the potential toxicity and potential allergenicity of Cry3Bb1 and CP4 EPSPS, and compositional analyses that focus on the food derived from MON 88017 corn have been provided. In addition to information supplied by the Applicant, the assessment will also entail the use of other available resource material including 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. Some food ingredients derived from MON 88017 corn may contain novel DNA and/or protein, and therefore would be required to be labelled as GM.

## **6. Regulatory Options**

### **6.1 Option 1 – prohibit food from insect-protected, glyphosate-tolerant corn line 88017**

Maintain the *status quo* by not amending the Code to approve the sale and use of food derived from insect-protected, glyphosate-tolerant corn line 88017.

### **6.2 Option 2 – approve food from insect-protected, glyphosate-tolerant corn line 88017**

Amend the Code to permit the sale and use of food derived from insect-protected, glyphosate-tolerant corn line 88017, with or without listing special conditions of use in the Table to clause 2 of Standard 1.5.2.

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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.

## **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 MON 88017 corn in the United States agricultural markets in the future, the approval of this application would ensure corn or food imports from the US to Australia and New Zealand would comply with the Code. There is no current intention to grow MON 88017 corn in Australia or New Zealand. Should this be decided in the future, any environmental impact would require assessment 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 Fisheries (MAF) before cultivation in these countries could be permitted.

### **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 corn line 88017 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 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 corn line 88017.

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.

This decision may impact on monitoring resources, as food derived from corn line 88017 will be required to be labelled as GM.

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.

Possible cost to food industry as some food ingredients derived from corn line 88017 will be required to be labelled as genetically modified.

**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 Consultation**

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 corn line 88017;**
- **Parties that might be affected by having this application approved or rejected;**
- **Arguments in support or opposition to permitting food from corn line 88017; and**
- **Potential costs and benefits to consumers, industry and government.**

### **8.2 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.

There are not any relevant international standards for this application, and amending the Code to allow food derived from corn line 88017 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 corn line 88017. 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 insect-protected, herbicide-tolerant corn line 88017. 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 corn line 88017;
- 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 corn line 88017 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 application and the preparation of a Draft Assessment Report.