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

5-05
3 August 2005

INITIAL ASSESSMENT REPORT

APPLICATION A564

FOOD DERIVED FROM INSECT-PROTECTED CORN LINE MIR604

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 14 September 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

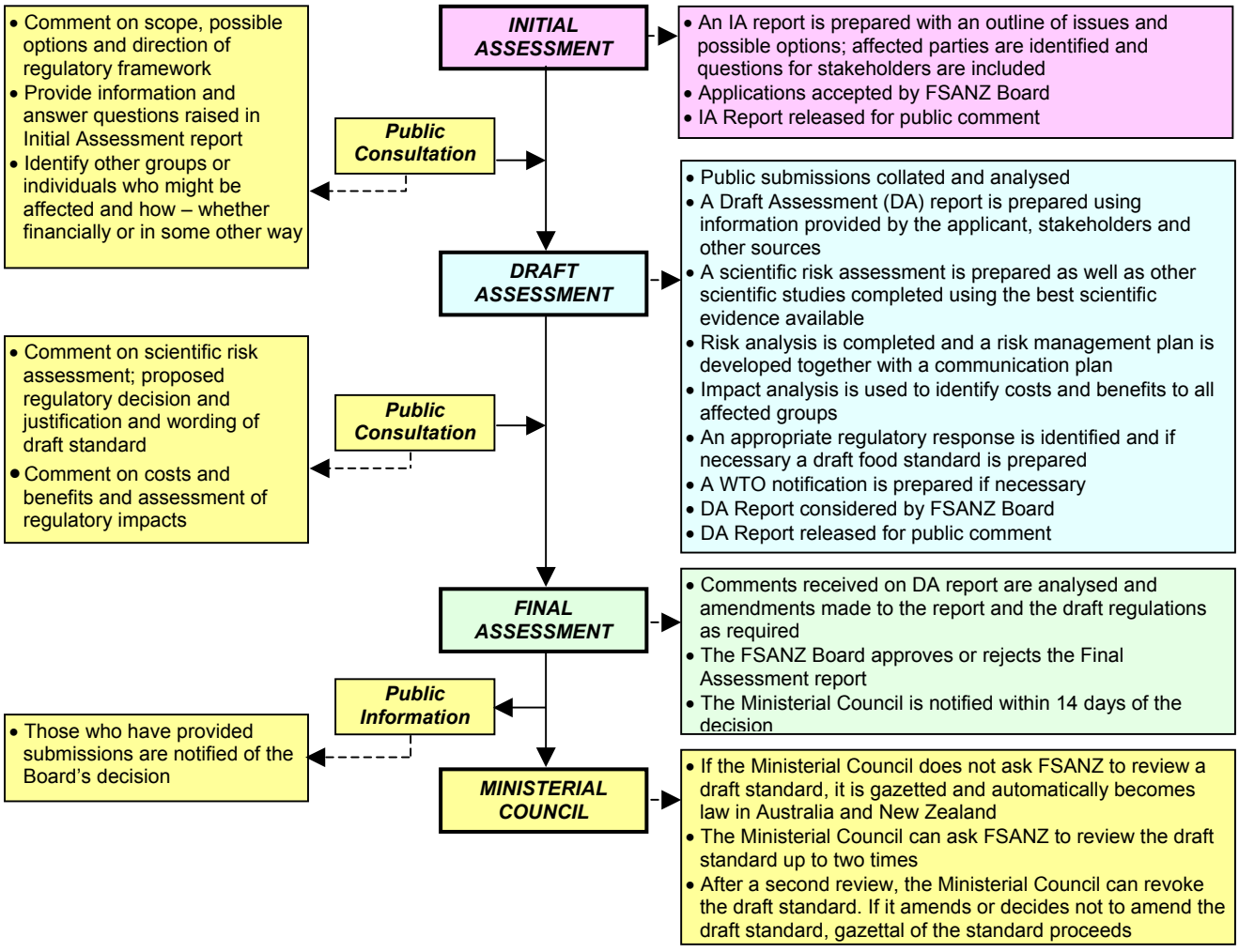
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 A564, 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

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) 14 September 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.

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.

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Executive Summary

An Application has been received from Syngenta Seeds Pty Ltd to amend the *Australia New Zealand Food Standards Code* (the Code) to approve food derived from a genetically modified (GM) corn, corn line MIR604. 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.

Corn line MIR604 has been genetically modified to be resistance to Western corn rootworm, Northern corn rootworm and Mexican corn rootworm. Resistance is conferred by expression of the *mCry3A* gene in the corn plants. A selectable marker gene, *pmi*, encodes phosphomannose isomerase and allows transformed corn cells to utilise carbon from phosphomannose media.

If approved, food from corn line MIR604 may enter Australia and New Zealand as imported products.

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

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 corn line MIR604.

1. Introduction

An Application was received from Syngenta Seeds Pty Ltd on 1 June 2005 seeking approval for food derived from insect-protected corn line MIR604 under Standard 1.5.2 – Food Produced Using Gene Technology, in the Code.

The genetic modification involved the transfer of the following genes into the corn plant:

- the *mCry3A* gene derived from *Bacillus thuringiensis* which encodes the insecticidal protein mCry3A. This protein is selectively toxic to coleopterans including Northern, Western and Mexican corn root worm; and

- the *pmi* gene which encodes phosphomannose isomerase and was used as a selectable marker as plants expressing this gene can utilise mannose as a primary carbon source, whereas cells lacking this gene will fail to proliferate on mannose-based medium.

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.

Before food derived from corn line MIR604 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 (ANZFRMC). An amendment to the Code may only be gazetted, once the Ministerial Council process has been finalised.

Syngenta Seeds Pty Ltd has therefore applied to have Standard 1.5.2 amended to include food derived from corn line MIR604 in the Table to clause 2.

3. Objective

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 corn line MIR604 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. Background

The Applicant has developed corn plants that are resistant to insect attack. These corn plants are referred to as corn line MIR604. The purpose of the modification is to provide growers with an effective method for controlling certain insect pests of corn.

Corn line MIR604 contains one insecticidal gene (*mCry3A*), derived from the common soil bacterium *Bacillus thuringiensis* (*Bt*). This gene expresses the insecticidal protein Cry3A, which is toxic to coleopteran insects, including three significant pests of corn: Western corn rootworm (*Diabrotica vigifera*), Northern corn rootworm (*Diabrotica berberi*) and Mexican corn rootworm (*Diabrotica vigifera zeae*).

In addition, corn line MIR604 contains the *pmi* gene from *Escherichia coli*, which produces an enzyme (phosphomannose isomerase) that allows the plants to utilise mannose as a sole source of carbon.

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 in industrial products, such as ethyl alcohol by fermentation and highly refined starch by wet-milling.

Domestic production of corn in Australia and New Zealand is supplemented by the import of a small amount of corn-based products, largely as 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 corn products such as cornstarch are also imported and used by the food industry for the manufacture of dessert mixes and canned foods.

Applications to permit the use of corn line MIR604 for food and feed use in the United States, Canada, Japan, the European Union and South Africa have been make. No approvals have been granted to date.

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.

5. Relevant Issues

5.1 Safety assessment of food from corn line MIR604

Food from corn line MIR604 will be evaluated according to the safety assessment guidelines prepared by FSANZ[1]. 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 corn line MIR604.

The Applicant has submitted a comprehensive data package in support of their application and has provided studies on the molecular characterisation of the insert in line MIR604, the toxicity and potential allergenicity of mCry3A and PMI, and compositional analyses of food derived from corn line MIR604. 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.

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. Food products from corn line MIR604 may contain DNA and/or protein. These products would be required to be labelled as GM.

6. Regulatory Options

6.1 Option 1 – prohibit food from insect-protected corn line MIR604

Maintain the *status quo* by not amending the Code to approve the sale and use of food derived from insect-protected corn line MIR604.

6.2 Option 2 – approve food from insect-protected corn line MIR604

Amend the Code to permit the sale and use of food derived from insect-protected, glufosinate corn line MIR604, 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

- 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 corn line MIR604 may 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 Fisheries (MAF) in New Zealand 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 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.

Cost associated with higher retail prices for segregated foods.

No impact on consumers wishing to avoid GM foods, as food from corn line MIR604 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 production for some sectors of the food industry. Cost to the food industry to source 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 if production efficiencies result in savings to producers, to the extent that savings are passed on.

Benefit of access to a greater range of products including imported food products containing ingredients derived from corn line MIR604.

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 MIR604 will be required to be labelled as GM.

Industry: 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 food derived from corn line MIR604 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

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 FANZ 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.

Comments that would be useful could cover:

- Scientific aspects of this application, in particular, information relevant to the safety assessment of food from corn line MIR604;
- Parties that might be affected by having this application approved or rejected;
- Arguments in support or opposition to permitting food from corn line MIR604; and
- Potential costs and benefits to consumers, industry and government.

All stakeholders must observe the relevant due date for submissions.

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 no relevant international standards and amending the Code to allow food derived from corn line MIR604 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 MIR604. 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 insect-protected, herbicide-tolerant corn line MIR604. 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 MIR604.

- 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 MIR604 would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.

- 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.

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.