

INITIAL ASSESSMENT REPORT

APPLICATION A518

FOOD DERIVED FROM INSECT PROTECTED COTTON LINE MXB-13

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
11 February 2004
(See 'Invitation for Public Submissions' for details)

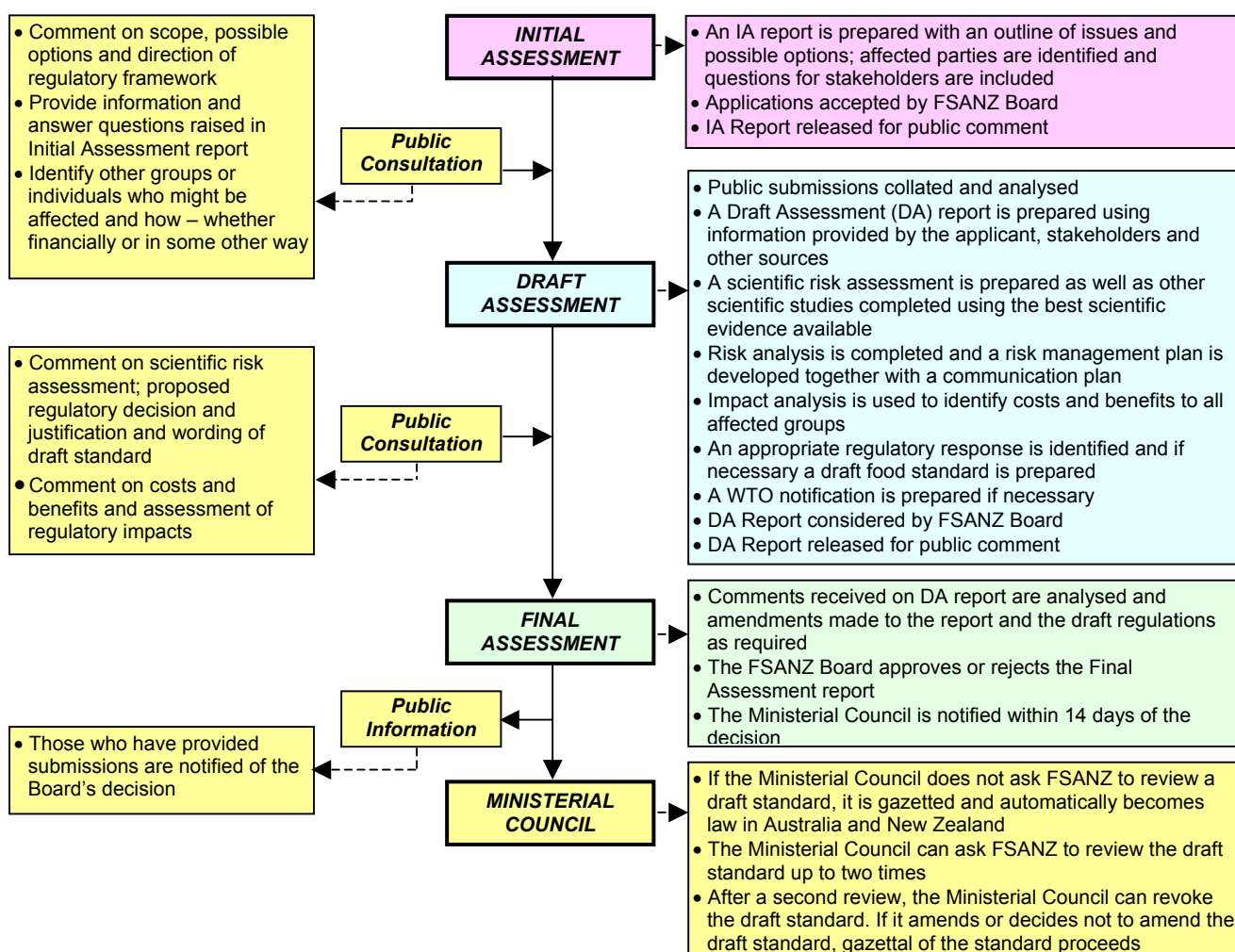
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Commonwealth; 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 Commonwealth, 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 Commonwealth, 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 A518, 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 should be received by FSANZ **by 11 February 2004**

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

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 Liaison 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.

CONTENTS

EXECUTIVE SUMMARY	6
1. INTRODUCTION.....	8
2. REGULATORY PROBLEM.....	8
3. OBJECTIVE	8
4. BACKGROUND	9
4.1 WORK PLAN CLASSIFICATION	10
5. RELEVANT ISSUES	10
5.1 SAFETY ASSESSMENT OF FOOD FROM COTTON LINE MXB-13	10
5.2 LABELLING	11
6. REGULATORY OPTIONS.....	11
OPTION 1 – PROHIBIT FOOD FROM INSECT-PROTECTED COTTON LINE MXB-13	11
OPTION 2 – APPROVE FOOD FROM INSECT-PROTECTED COTTON LINE MXB-13.....	11
7. IMPACT ANALYSIS	11
7.1 AFFECTED PARTIES	11
7.2 IMPACT ANALYSIS.....	12
8. CONSULTATION	13
8.1 PUBLIC CONSULTATION	13
8.2 WORLD TRADE ORGANIZATION (WTO)	14
9. CONCLUSION AND RECOMMENDATION	14

Executive Summary

An application has been received from Dow AgroSciences Australia Pty. Ltd. to amend the *Australia New Zealand Food Standards Code* (the Code) to approve food derived from a genetically modified (GM) insect-protected cotton, cotton line MXB-13. 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. This is a cost recovered application.

This Initial Assessment Report is not an assessment of the merits of the Application but rather is an assessment of whether the application should be accepted for further consideration, according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act). This Application has been assessed against the requirements for Initial Assessment of section 13 of the FSANZ Act, and it is recommended that this Application be accepted and progressed to Draft Assessment for the following reasons:

- The Application seeks to amend the Code to include food derived from cotton line MBX-13.
- The permitted GM foods are listed in the Table to clause 2 of Standard 1.5.2. There is currently no permission for food derived from cotton line MXB-13.
- Therefore, if further assessment of food derived from cotton line MXB-13 shows it to be safe for human consumption, this Application relates to a matter that warrants a variation to Standard 1.5.2.
- 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 cotton line MXB-13 would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.
- FSANZ believes an assessment of the potential public health and safety concern relating to food derived from cotton line MXB-13 is the only measure available to ensure public health and safety.

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, now that it has been accepted. The information needed to complete the assessment will include information received from public submissions.

There is currently no approval for the sale and use of food from cotton line MXB-13. If this application is successful, FSANZ will amend the Code and insert a permission to use food from cotton line MXB-13 in the Table to clause 2 of Standard 1.5.2.

Cotton line MXB-13 has been genetically modified for protection against the cotton bollworm (*Heliothis zea*), tobacco budworm (*H. virescens*) and pink bollworm (*Pectinophora gossypiella*), significant pests of cotton crops in Australia. Protection is conferred by the expression in the plant of bacterially derived protein toxins (*Bt*- δ endotoxins) that are specific for these insects. Cotton line MXB-13 also contains two copies of a gene encoding resistance to the herbicide glufosinate ammonium.

Cotton line MXB-13 has been developed for cultivation in North America and Australia. Therefore, food derived from cotton line MXB-13 may enter the food supply in Australia and New Zealand via domestically produced and imported products.

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 cotton line MXB-13.

1. Introduction

An application was received from Dow AgroSciences Australia Pty Ltd on 6 November 2003 seeking approval for food derived from insect-protected cotton line MXB-13 under Standard 1.5.2 - Food Produced Using Gene Technology - in the Code.

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

- the *cry1Ac* and *cry1F* genes from *Bacillus thuringiensis* subspecies *kurstaki* and *aizawai* respectively, which express the insect-specific protein δ endotoxins Cry1Ac and Cry1F; and
- the phosphinothricin-acetyltransferase gene, *pat*, from *Streptomyces viridochromogenes*, expressing the enzyme phosphinothricin-acetyltransferase (PAT) which confers tolerance to the herbicide glufosinate ammonium.

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, once fully approved, are listed in the Table to clause 2 of the Standard.

Dow AgroSciences Australia Pty Ltd has developed a new variety of insect-protected cotton, known as MXB-13, 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 New Zealand Food Regulation Ministerial Council (ANZFRMC). An amendment to the Code may only be gazetted, once the Ministerial Council process has been finalised.

Dow AgroSciences Australia Pty Ltd has therefore applied to have Standard 1.5.2 amended to include food derived from MXB-13 cotton in the Table to clause 2.

3. Objective

The objective of this assessment is to determine whether the Code should be amended to approve food derived from cotton line MXB-13. The assessment will include consideration of the section 10 objectives of the FSANZ Act.

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.

In addressing the issue of approving the sale and use of food derived from cotton line MXB-13, the key objectives are 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 risk analysis using the best available scientific evidence and the desirability of an efficient and internationally competitive food industry.

4. Background

Cotton line MXB-13 contains two insecticidal genes (*cry1Ac* and *cry1F*), derived from the common soil bacterium *Bacillus thuringiensis* (*Bt*). These genes express insecticidal proteins (*Cry1Ac* and *Cry1F*) that are toxic to specific lepidopteran caterpillar insects, including the major pests of cotton. The insecticidal genes were introduced separately into two cotton lines (*MXB-7* and *MXB9*) and these two traits were subsequently combined by crossing the two GM cotton lines to produce cotton line *MXB-13*.

The main purpose of the genetic modification is to confer protection against the cotton bollworm (*Heliothis zea*), tobacco budworm (*H. virescens*) and pink bollworm (*Pectinophora gossypiella*). Using two *Bacillus thuringiensis* derived insecticidal proteins in the same plant improves the spectrum of control, the seasonal efficacy and significantly reduces the chances of selecting insects resistant to the toxins. *Bt* formulations are widely used as biopesticides on a variety of cereal and vegetable crops grown organically or under conventional agricultural conditions.

In addition, *MXB-13* contains two copies of a selectable marker gene (*pat*) from the bacterium *Streptomyces viridochromogenes*, which produces an enzyme (phosphinothricin acetyltransferase, *PAT*) that detoxifies the herbicide glufosinate ammonium. *PAT* functions as a selectable marker in the initial laboratory stages of plant cell selection and thus *MXB-13* is also tolerant to the herbicide glufosinate ammonium.

Cottonseed is processed into four major by-products: oil, meal, hulls and linters. Only the oil and the linters are used in food products. Cottonseed oil is used in a variety of food including cooking, salad and frying oils: mayonnaise, salad dressing, shortening, margarine and packaging oils. Cotton linters are used as a cellulose base in high fibre dietary products as well as viscosity enhancers in toothpaste, ice cream and salad dressing. Cottonseed meal is primarily used for stock food and is not currently sold for human consumption in Australia or New Zealand.

Cotton line MXB-13 is being developed for cultivation in Australia and the USA. The Applicant has applied to the Office of the Gene Technology Regulator (OGTR) for a licence for field trials of this cotton (DIR 40/2003). This application is currently being assessed by the OGTR. None of the plants produced during the field trials will enter the human food chain.

In addition, an application to permit the use of cotton line MXB-13 for food and feed use in the United States has been submitted to the USDA, the US EPA and the FDA.

4.1 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 categories. 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 cotton line MXB-13

Food from cotton line MXB-13 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;
- a consideration of the safety of any transferred antibiotic resistance genes;
- characterisation of any novel proteins, including their potential toxicity and allergenicity;
- a comparative analysis of the key constituents of cotton line MXB-13.

The Applicant has submitted a comprehensive data package in support of their application and has provided studies on the molecular characterisation of the two insertions in MXB-13, the toxicity and potential allergenicity of Cry1Ac, Cry1F and PAT, and compositional analyses of food derived from cotton line MXB-13. 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.

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

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 only food use of cotton is the cottonseed oil and linters, neither of which contain DNA or protein. These products would therefore not be required to be labelled.

6. Regulatory Options

Option 1 – prohibit food from insect-protected cotton line MXB-13

Maintain the *status quo* by not amending the Code to approve the sale and use in food of oil and linters derived from cotton line MXB-13.

Option 2 – approve food from insect-protected cotton line MXB-13

Amend the Code to permit the sale and use in food of oil and linters derived from cotton line MXB-13, with or without listing special conditions 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.

The cultivation of cotton line MXB-13 may have an impact on the environment, which would need to be assessed by the Office of the Gene Technology Regulator (OGTR) before cultivation in Australia could be permitted. The applicant has indicated that they do intend to undertake field trials of cotton line MXB-13 in Australia in the future and have applied for a license from the OGTR to do so.

If planting in New Zealand ever became likely, a comprehensive environmental risk analysis would be required by various New Zealand government agencies including as the Environmental Risk Management Authority (ERMA) and the Ministry of Agriculture and Fisheries (MAF) in New Zealand.

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.

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 cotton line MXB-13 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.

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 MXB-13.

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 is unlikely to impact on monitoring resources.

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

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 Consultation

The Initial Assessment Report is intended 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 cotton line MXB-13;
- Parties that might be affected by having this application approved or rejected;

- Arguments in support or opposition to permitting food from cotton line MXB-13; 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 and amending the Code to allow food derived from cotton line MXB-13 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 MXB-13. 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. 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.