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

7 April 2010
[9-10]

APPLICATION A1029
FOOD DERIVED FROM DROUGHT-TOLERANT CORN LINE MON87460
2nd ASSESSMENT REPORT

Executive Summary

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Limited (Monsanto) on 10 June 2009. The Applicant requested an amendment to Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code), to permit the sale and use of food derived from a new genetically modified (GM) variety of corn, drought-tolerant corn line MON87460 (referred to as MON87460 corn). Standard 1.5.2 prohibits a food produced using gene technology from being sold or used as an ingredient or component of any food unless it is listed in the Table to clause 2 of that Standard.

MON87460 corn has been genetically modified to tolerate cultivation under water-limited conditions. The trait is conferred by expression of a single bacterial gene encoding cold shock protein B. The corn line also contains a commonly used marker gene encoding antibiotic resistance.

MON87460 corn is intended for cultivation in North America. However, once commercialised, corn products imported into Australia and New Zealand could contain ingredients derived from MON87460 corn. Approval is therefore necessary before these products may enter the Australian and New Zealand markets.

This Application is being assessed under the Major Procedure, which includes two rounds of public consultation. FSANZ has considered all submissions received in the 1st consultation period and has addressed issues, particularly those relevant to the safety of food derived from MON87460 corn. Where necessary, additional information has been incorporated into this 2nd Assessment Report.

Safety Assessment

FSANZ has completed a comprehensive safety assessment of food derived from MON87460 corn, which was released in the 1st Assessment Report. This assessment included consideration of (i) the genetic modification to the plant; (ii) the potential toxicity and allergenicity of the novel proteins; and (iii) the composition of MON87460 corn compared with that of conventional corn varieties.

No public health and safety concerns were identified as a result of the safety assessment.

On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from drought-tolerant MON87460 corn is considered as safe and wholesome as food derived from other commercial corn varieties.

Labelling

If approved, food derived from MON87460 corn will be required to be labelled as genetically modified if novel DNA and/or novel protein are present in the final food. Studies conducted by the Applicant show that novel proteins are present in the grain.

Labelling addresses the objective set out in paragraph 18(1)(b) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act); that is, the provision of adequate information relating to food to enable consumers to make informed choices. The general labelling requirements will provide consumers with information about the GM status of foods.

Impact of regulatory options

Following satisfactory completion of the safety assessment, two regulatory options were considered: (1) no approval; or (2) approval of food derived from MON87460 corn.

Following analysis of the potential costs and benefits of each option on affected parties (consumers, the food industry and government), option 2, approval of this Application, is the preferred option. Under option 2, the potential benefits to all sectors outweigh the costs associated with the approval.

Assessing the Application

In assessing the Application, FSANZ has had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- Whether costs that would arise from an amendment to the Code approving food derived from MON87460 corn do not outweigh the direct and indirect benefits to the community, Government and industry that would arise from the development or variation of the food regulatory measure
- 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
- There are no relevant New Zealand standards
- Any other relevant matters.

Preferred Approach

To prepare a draft variation to Standard 1.5.2 – Food produced using Gene Technology, to include food derived from drought-tolerant corn line MON87460 in the Table to clause 2.

Reasons for Preferred Approach

The development of a draft variation to the Code to give approval to the sale and use of food derived from MON87460 corn in Australia and New Zealand is proposed on the basis of the available scientific evidence, for the following reasons:

- the safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce MON87460 corn
- food derived from MON87460 corn is equivalent to food from the conventional counterpart and other commercially available corn varieties in terms of its safety for human consumption and nutritional adequacy
- labelling of certain foods derived from MON87460 corn will be required if novel DNA and/or protein is present in the final food
- a regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is Option 2, an amendment to the Code
- there are no relevant New Zealand standards
- 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.

Consultation

Consultation on the 1st Assessment was conducted over a period of eight weeks; twenty-five submissions were received. Summaries of these are in Attachment 2 of this Report. FSANZ has taken all submitters' comments into consideration in completing the 2nd Assessment Report. Specific issues relating to the safety of food derived from MON87460 corn have been addressed. Public comment is now invited on this Report, which includes a draft variation to Standard 1.5.2. Comments received in the second consultation period will be used to assist in preparing the Approval Report, to complete the assessment of the Application.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variation/s to the Code based on regulation impact principles for the purpose of preparing a variation to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 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, separate it from your submission and provide justification for treating it as confidential commercial material.

Section 114 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. 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 Changing the Code tab and then through Documents for Public Comment.

Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 5 May 2010

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if 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.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy 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

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 978 5636

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SUPPORTING DOCUMENTS

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at
http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa1029food4367.cfm

SD1: Safety Assessment Report (AMENDED)

INTRODUCTION

On 10 June 2009, Monsanto Australia Limited (Monsanto) submitted an Application seeking approval for food derived from drought-tolerant corn line MON87460 (referred to as MON87460 corn) under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

MON87460 corn has been genetically modified (GM) to tolerate cultivation under water-limited conditions. Although MON87460 corn is still susceptible to drought conditions, the level of yield loss is less than conventional corn. The drought tolerance trait is conferred by expression of a single gene, *cspB*, from *Bacillus subtilis*, which encodes cold shock protein B (CSPB). Cold shock proteins are widely found in bacteria and facilitate adaption to suboptimal temperatures by essentially preserving protein synthesis. Similar proteins are also found in plants and enable them to tolerate various abiotic stresses.

The GM corn line also contains a commonly used antibiotic resistance marker gene (ARMG), *nptII* (neomycin phosphotransferase type II) from the ubiquitous gut bacterium, *Escherichia coli* that confers resistance to the antibiotics, neomycin and kanamycin. The ARMG enabled the identification and selection of GM plant tissue during the initial stage of development of the GM corn line in the laboratory.

The 1st Assessment Report included a full scientific evaluation of food derived from MON87460 corn according to FSANZ guidelines to assess its safety for human consumption. Following an eight week period of public consultation, the issues raised in submissions have been considered and addressed in this 2nd Assessment. Additional information has been included in the safety assessment (Supporting Document 1). Public comment is now sought on this 2nd Assessment Report, which includes the draft variation to Standard 1.5.2, prior to preparation of the Approval Report and completion of the Application. All submissions relating to the 1st Assessment have been summarised in Attachment 2 of this Report.

1. The Issue / Problem

The Applicant has developed MON87460 corn that is genetically modified to reduce yield loss under water-limited conditions. Pre-market approval is necessary before this product may enter the Australian and New Zealand food supply. An amendment to the Code granting approval to food derived from MON87460 corn must be approved by the FSANZ Board, and subsequently 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.

MON87460 corn is intended for cultivation in North America. Before release onto commercial agricultural markets, the Applicant is seeking regulatory approval for MON87460 corn in key trading markets for corn, including Australia and New Zealand. This is necessary because once it is cultivated on a commercial-scale, corn products imported into Australia and New Zealand could contain ingredients derived from MON87460 corn as a result of comingling practices at harvest or later processing stages. The Applicant has therefore sought the necessary amendments to Standard 1.5.2 to include food derived from MON87460 corn prior to any decision to commercialise this line. The Application is being assessed under the Major Procedure.

2. Current Standard

2.1 Background

Approval of GM foods under Standard 1.5.2 is contingent upon completion of a comprehensive pre-market safety assessment. Foods that have been assessed under the Standard, if approved, are listed in the Table to clause 2 of the Standard.

2.2 Overseas approvals

MON87460 corn is intended for commercialisation in the United States and Canada. The Applicant has stated that regulatory submissions have been made to the United States Food and Drug Administration (FDA) and the United States Department of Agriculture-Animal and Plant Health Inspection Service. The outcome of these approvals is pending. An application for authorisation of GM maize MON87460 for food and feed uses, import and processing is also currently being assessed by the European Commission.

The Applicant has advised that further submissions for import approvals in key international markets will also be made.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives, which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- 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.

RISK ASSESSMENT

Food derived from drought-tolerant MON87460 corn has been evaluated according to the safety assessment guidelines prepared by FSANZ[1] and is provided in **Supporting Document 1**. The summary and conclusions from the safety assessment are presented below.

[1] FSANZ (2007) Safety Assessment of Genetically Modified Foods – Guidance Document. http://www.foodstandards.gov.au/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf

In addition to information supplied by the Applicant, other available resource material including published scientific literature and general technical information was used in this assessment.

4. Risk Assessment Summary

4.1 Safety Assessment Process

In conducting a safety assessment of food derived from MON87460 corn, a number of criteria have been addressed including: a characterisation of the transferred *cspB* gene, its origin, function and stability in the corn genome; the changes at the level of DNA, protein and in the whole food; detailed compositional analyses; evaluation of intended and unintended changes; and the potential for the newly expressed proteins to be either allergenic or toxic in humans.

The safety assessment applied to food from MON87460 corn addresses only food safety and nutritional issues. It does not address any risks related to the release into the environment of GM plants used in food production, the safety of animal feed or animals fed with feed derived from GM plants, or the safety of food derived from the non-GM (conventional) plant.

4.2 Outcomes of the Safety Assessment

MON87460 corn contains two novel genes, *cspB* and *nptII*. Detailed molecular analyses indicated that one copy of each gene has been inserted at a single site in the corn genome. The *cspB* gene is stably inherited from one generation to the next.

Two novel proteins are expressed in MON87460 corn, namely CSPB and NPTII. While CSPB has not previously been assessed by FSANZ, it is likely that humans have already been exposed to it via contact with the source organism. In addition, humans are also likely to have been exposed to other bacterial cold shock proteins and their plant homologues.

CSPB is nearly identical to that present in the source organism except for a single amino acid substitution at position 2 (from leucine to valine) necessary for cloning purposes. CSPB is present in MON87460 corn grain at a mean concentration of 0.041 and 0.33 µg/g fresh weight under well-watered and water-limited conditions, respectively. The plant protein conforms in size and amino acid sequence to that expected, is immunoreactive to antibodies to CSPB, is not glycosylated, and exhibits the expected functional activity.

FSANZ has assessed NPTII on several previous occasions and an extensive database exists regarding its safety. The level of NPTII in corn grain was below the limit of quantitation (LOQ).

Bioinformatic studies with CSPB and NPTII confirmed the absence of any biologically significant amino acid sequence similarity to known protein toxins or allergens. Digestibility studies demonstrated that CSPB would be rapidly degraded following ingestion, similar to other dietary proteins. An acute oral toxicity study confirmed the absence of toxicity for CSPB. Taken together, the evidence indicates that neither protein is toxic nor likely to be allergenic in humans.

Compositional analyses of drought-tolerant MON87460 corn, which was cultivated under well-watered and water limited conditions, established its equivalence to conventional corn cultivated under the same conditions.

For all analysed components in forage and grain from MON87460 corn, there were no compositional differences of biological significance compared to conventional (non-GM) corn. The detailed compositional analysis was considered acceptable to establish the nutritional adequacy of food derived from MON87460 corn. The introduction of MON87460 corn into the food supply would therefore be expected to have little nutritional impact.

4.3 Conclusions

No potential public health and safety concerns have been identified in the assessment of drought-tolerant MON87460 corn. On the basis of the data provided in the present Application, and other available information, food derived from MON87460 corn is considered as safe and wholesome as food derived from conventional corn varieties.

RISK MANAGEMENT

5. Issues raised

5.1 Risk Management Strategy

In accordance with the general labelling provisions of Standard 1.5.2, food derived from drought-tolerant MON87460 corn, if approved, will be required to be labelled as genetically modified if novel DNA and/or novel protein are present in the final food. Studies conducted by the Applicant show that novel proteins are present in the grain. Highly refined products, such as corn oil, are exempt from this general labelling requirement where novel protein and/or novel DNA are removed during the refining process (refer to subclause 4(1)(c) of Standard 1.5.2).

As food derived from drought-tolerant MON8760 corn is equivalent to food from the conventional counterpart in terms of its composition and safety, FSANZ concludes that no additional labelling will be required in relation to the matters specified in clause 7 of Standard 1.5.2. The general labelling requirements will provide consumers with adequate information about the GM status of foods.

6. Options

There are no non-regulatory options for this Application. The two regulatory options available for this Application are:

6.1 Option 1 – Reject the Application

Maintain the *status quo* by rejecting the Application.

6.2 Option 2 – Prepare draft variations to the Code

Proceed to development of a food regulatory measure to amend Standard 1.5.2 to permit the sale and use of food derived from drought-tolerant corn line MON87460, with or without specified conditions attached.

7. 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.

7.1 Affected Parties

The affected parties may include the following:

- Consumers of corn-containing food products, particularly those concerned about the use of biotechnology to generate new crop varieties.

- Industry sectors:

  - food importers and distributors of wholesale ingredients
  - processors and manufacturers of corn-containing food products
  - food retailers.

- Government:

  - enforcement agencies
  - national Governments, in terms of trade and World Trade Organization (WTO) obligations.

MON87460 corn has been developed primarily for agricultural production overseas and at this stage the Applicant has no plans for cultivation of this variety in either Australia or New Zealand. The cultivation of MON87460 corn in Australia or New Zealand could have an impact on the environment, which would need to be independently 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 Forestry (MAF) before commercial release in either country could be permitted.

7.2 Benefit Cost Analysis

7.2.1 Option 1 – reject the Application

Consumers: Possible restriction in the availability of imported corn products to those products that do not contain MON87460 corn.

No impact on consumers wishing to avoid GM foods, as food from MON87460 corn is not currently permitted in the food supply.

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

Industry: Possible restriction on imports of corn food products once MON87460 corn is commercialised overseas.

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

7.2.2 Option 2 – prepare draft variations to the Code

Consumers: Broader availability of imported corn products as there would be no restriction on imported foods containing MON87460 corn.

Potentially, no increase in the prices of imported foods manufactured using comingled corn products.

Appropriate labelling would allow consumers wishing to avoid GM corn to do so.

Government: Benefit that if MON87460 corn was detected in corn imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of MON87460 corn would ensure no conflict with WTO responsibilities.

This option could impact on monitoring resources, as certain foods derived from MON87460 corn will be required to be labelled as genetically modified.

Industry: Importers of processed foods containing corn derivatives would benefit as foods derived from MON87460 corn would be compliant with the Code, allowing broader market access and increased choice in raw materials.

Retailers may be able to offer a broader range of corn products or imported foods manufactured using corn derivatives.

Possible cost to food industry as some food ingredients derived from MON87460 corn would be required to be labelled as genetically modified.

7.3 Comparison of Options

As food from drought-tolerant MON87460 corn has been found to be as safe as food from conventional varieties of corn, Option 1 is likely to be inconsistent with Australia's and New Zealand's WTO obligations.

Option 1 would also offer little benefit to consumers, as approval of MON87460 corn by other countries could limit the availability of imported corn products in the Australian and New Zealand markets. In addition, Option 1 would result in the requirement for segregation of any products containing MON87460 corn from those containing approved corn varieties, which would be likely to increase the costs of imported corn foods.

Based on the conclusions of the safety assessments, the potential benefits of Option 2 outweigh the potential costs. A variation to Standard 1.5.2 giving approval to drought-tolerant MON87460 corn is therefore the preferred option.

COMMUNICATION AND CONSULTATION STRATEGY

8. Communication

FSANZ has applied a basic communication strategy to this Application that involves advertising the availability of assessment reports for public comment in the national press and placing the reports on the FSANZ website. In addition, FSANZ will issue a media release drawing journalists' attention to the matter.

As normally applies to all GM food assessments, this 2nd Assessment Report will be available to the public on the FSANZ website and distributed to major stakeholders.

Public comments on this 2nd Assessment will be used in preparing an Approval Report that will be considered by the FSANZ Board.

The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the assessment. After the FSANZ Board has considered the Approval Report, if the draft variation to the Code is approved, that decision will be notified to the Ministerial Council. If the approval of food derived from drought-tolerant MON87460 corn is not subject to review, the Applicant and stakeholders, including the public, will be notified of the gazettal of changes to the Code in the national press and on the website.

9. Consultation

9.1 Public consultation

Public submissions were invited on the 1st Assessment Report between 16 December 2009 and 10 February 2010. Comments were specifically sought on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from drought-tolerant MON87460 corn. Comments on the proposed labelling requirements for food derived from MON87460 corn were also invited. Twenty-five submissions were received. A summary of these is provided in **Attachment 2** to this Report. Responses to the main issues raised regarding any risks to human safety if MON87460 corn was to be approved for food use, are provided below. Where necessary, FSANZ has addressed the issue through a change to the Safety Assessment Report for MON87460 corn.

As this Application is being assessed under the Major Procedure, there are two rounds of public comment. Submissions from the public are invited on this 2nd Assessment Report, including the proposed draft variations to the Code.

9.1.1 General issues

Some stakeholders have asked that FSANZ not approve any GM foods. It must be acknowledged however that FSANZ has a statutory obligation to consider all applications seeking to amend the Code on their individual merits, subject to the application meeting detailed criteria concerning format and inclusion of information. An open and transparent process of assessment is then used to develop or amend food standards as may be appropriate in Australia and New Zealand. In particular, public consultation periods are considered integral to this process, and comments received from submitters contribute to the overall effectiveness of the risk assessment.

While the FSANZ assessment of GM foods is guided by concepts and principles developed through the work of the OECD, FAO, WHO and the Codex Alimentarius Commission, the *FSANZ Safety Assessment of Genetically Modified Foods* (see Footnote 1) and the *Application Handbook*[2] are the primary references relevant to GM food safety assessments in Australia and New Zealand. The data submitted in support of an application and the conduct of all studies is subject to strict requirements as outlined in the *Application Handbook*. All unpublished studies are independently assessed by FSANZ based on their scientific merits.

[2] http://www.foodstandards.gov.au/_srcfiles/Application%20Handbook%20as%20at%2025%20August%202009.pdf

During public consultation on the 1st Assessment Report for MON87460 corn, the following general issues were raised concerning GM foods and their assessment:

- lack of independent data on the safety of GM food, including long-term feeding studies
- horizontal gene transfer of antibiotic resistance genes
- stability of transgenes in the digestive tract
- post-market monitoring of GM foods
- labelling of GM food
- environmental impact of GM crops.

The majority of these issues have been addressed by FSANZ in previous applications and in addition, specific information is available on the FSANZ website (Table 1). It should be noted that there is no intent to grow MON87460 corn in Australia or New Zealand. If this was to be the case then the Applicant would need to apply to the Office of the Gene Technology Regulator (OGTR) (Australia) and/or the New Zealand Ministry of Agriculture and Forestry (MAF) for approval.

Table 1: Information regarding GM food on the FSANZ website

Issue	Web link
Safety assessment of GM food	http://www.foodstandards.gov.au/_srcfiles/GM%20Foods_text_pp_final.pdf http://www.foodstandards.gov.au/consumerinformation/gmfoods/frequentlyaskedquestionsongeneticallymodifiedfoods/
Lack of independent data to inform the risk assessment	http://www.foodstandards.gov.au/consumerinformation/gmfoods/ http://www.foodstandards.gov.au/consumerinformation/gmfoods/frequentlyaskedquestionsongeneticallymodifiedfoods/part2safetyassessmen4658.cfm
The need for long-term animal feeding studies	http://www.foodstandards.gov.au/consumerinformation/gmfoods/ http://www.foodstandards.gov.au/consumerinformation/gmfoods/frequentlyaskedquestionsongeneticallymodifiedfoods/part2safetyassessmen4658.cfm http://www.foodstandards.gov.au/foodmatters/gmfoods/roleofanimalfeedings3717.cfm http://www.foodstandards.gov.au/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf
Stability of transgenes to digestion	http://www.foodstandards.gov.au/educationalmaterial/factsheets/factsheets2008/gmfoodssafetyofinges4072.cfm
Horizontal gene transfer/antibiotic resistance genes	http://www.foodstandards.gov.au/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf http://www.foodstandards.gov.au/_srcfiles/GM%20Foods_text_pp_final.pdf
Post-market monitoring	http://www.foodstandards.gov.au/consumerinformation/gmfoods/frequentlyaskedquestionsongeneticallymodifiedfoods/part2safetyassessmen4658.cfm

Issue	Web link
Labelling	http://www.foodstandards.gov.au/_srcfiles/GM%20Foods_text_pp_final.pdf http://www.foodstandards.gov.au/consumerinformation/gmfoods/frequentlyaskedquestionsongeneticallymodifiedfoods/part3labellingofgmfo4659.cfm

9.1.2 Specific issues

A number of issues specific to the assessment of MON87460 corn were raised in submissions and are addressed in the following responses. Where necessary, amendments have been made to the Safety Assessment Report.

9.2.1.1 Effect of MON87460 corn on normal cellular ageing processes, neuronal development and memory has not been addressed

There is no evidence in the scientific literature to suggest that consumption of food from any GMO, including GM corn, has been implicated in cellular ageing, adverse effects on the nervous system or cognitive function.

9.2.1.2 Mechanism of drought tolerance in MON87460 corn and its effect on normal metabolism

Information contained in the Safety Assessment Report contained an up-to-date review of the biology of cold shock proteins, including the mechanism of action of CSPB. As discussed in Section 4.1.1 of the Safety Assessment Report, CSPB is an RNA chaperone, which preserves the integrity of protein synthesis under conditions of abiotic stress, such as drought. An updated scientific literature search conducted as part of this 2nd Assessment Report found no further information on the precise mechanism of CSPB-induced, drought-tolerance in MON87460 corn. It is worth noting, however, that compositional analysis established the equivalence of MON87460 to conventional corn when grown under well-watered and water-limited conditions confirming that normal plant metabolism was not disrupted by the expression of CSPB (Section 5, Safety Assessment Report).

9.2.1.3 Identity of the control corn line used as the comparator in the compositional analysis study

FSANZ can confirm that corn line DM1718, which was used in the compositional analysis study, is a conventional isogenic control and not a null segregant. LH59 is an inbred corn line, which was transformed with plasmid PV-ZMAP595 to generate MON87460 corn. According to the breeding tree provided in the Safety Assessment Report (Figure 4), MON87460 corn (LH59R4) was crossed with the inbred corn line, 01DKD. The control corn line, DM1718, is a cross of the two conventional inbreds, LH59 and 01DKD2 (LH59 x 01DKD2), noting that LH59 was not transformed with plasmid PV-ZMAP595.

9.2.1.4 Expression of the novel open reading frame (ORF) encoding peptide 5_2 in MON87460 corn

The Applicant undertook bioinformatic analysis of the flanking sequences to ascertain whether theoretical proteins generated from ORFs at the 5' and 3' insert/corn junctions could be potentially toxic, allergenic or biologically active (see Section 3.4.3 or the Safety Assessment Report). In the absence of biologically relevant sequence homology with known toxins, allergens or biologically active proteins, none of the nine theoretical proteins, including peptide 5_2, were concluded to pose a hazard to human health.

Despite this, one submitter requested evidence that peptide 5_2 is not expressed at any life stage or in any tissue of MON87460 corn. Another submitter considered that the analysis of upstream regulatory elements would strengthen the conclusions regarding the expression of putative peptides spanning the 5' and 3' insert/corn junctions.

To reiterate the Safety Assessment Report, the bioinformatic analysis undertaken was theoretical, with the results indicating that in the highly unlikely event that any ORF were to be translated, or that the reverse complement strand of the *cspB* and *nptII* coding sequences were transcribed and translated, the translation product would not share a sufficient degree of sequence similarity or identity to indicate that it would be potentially allergenic, toxic, or have other health implications. The bioinformatic analysis of the insert junctions considered any sequence between two stop codons that would theoretically correspond with a peptide eight or more amino acids in length. This is a highly conservative approach that assumes transcription and translation are possible and does not consider whether such events are probable. Translation of these putative peptides is in fact improbable given that the sequence is located between two stop codons. Given the nature of the bioinformatic analysis and its results, no further studies are considered necessary.

9.2.1.5 Generation of transcriptional or translational products from potential ORFs resulting from site specific recombination events at the loxP sites inserted into MON87460 corn

As described in Section 3.1 of the Safety Assessment Report, the *nptII* gene present in MON87460 corn is flanked by *loxP* sites to allow the potential excision of the gene by *Cre* recombinase, a type I topoisomerase from bacteriophage P1. *Cre* recombinase catalyses the site-specific recombination of DNA between *loxP* sites[3]. The corollary of this is that recombination does not occur without *Cre* recombinase being present.

Given that the gene for *Cre* recombinase from bacteriophage P1 was not introduced into MON87460 corn, there is no potential for site specific recombination events at the *loxP* sites in MON87460 corn.

9.2.1.6 Additional evidence for digestibility of CSPB:nucleic acid complexes

Cold shock protein genes and their encoded proteins are ubiquitous in the environment by virtue of their presence in bacteria, plants and animals, including humans, where they function as nucleic acid chaperones [recently reviewed by Chaikam & Karlson (2010)[4]]. The functional unit of cold shock proteins is the so-called cold shock domain (CSD), which is a highly conserved nucleic acid binding domain. Humans would already be exposed to a variety of CSD-containing proteins in the diet in both the complexed and uncomplexed form, including bacterially-derived CSPB, and these would be subject to the same digestive processes as all dietary proteins and nucleic acids.

With the exception of the single amino acid substitution at the N-terminus, the sequence of MON87460-derived CSPB is identical to the source organism (*B. subtilis*) and therefore its binding to single stranded nucleic acid (via the CSD) would be no more stable (or unstable) to digestion, cooking or processing. On this basis there is no *a priori* reason to consider that CSPB:nucleic acid complexes derived from MON87460 corn would behave differently to bacterially-derived CSPB:nucleic acid complexes that humans are already exposed to.

[3] Abremski K & Hoess R (1984) Bacteriophage P1 Site-specific recombination. Journal of Biological Chemistry 259(3): 1509-1514.
[4] Chaikam V & Karlson DT (2010) Comparison of structure, function and regulation of plant cold shock domain proteins to bacterial and animal cold shock domain proteins. BMB Reports 43(1): 1-8.

As discussed in Section 4.1.1 and 4.5.3 of the Safety Assessment Report, the susceptibility of CSPB to *in vitro* trypsin digestion is reduced in the presence of nucleic acid at pH 8.6 and 25°C (Schindler et al 1999). This reduction is not equivalent to complete protection as may have been implied in the Safety Assessment Report as the protein is still degraded albeit more slowly. In the context of the suite of proteases present in the human digestive tract, which have different specificities to trypsin (e.g. pepsin, chymotrypsin, carboxypeptidase), it is highly unlikely that CSPB:nucleic acid complexes could evade dissociation and digestion. Further, the utility of the *in vitro* study by Schindler et al (1999) to the possible behaviour of CSPB:nucleic acid complexes in the low pH of the gastric environment is questionable.

9.2.1.7 Compliance with the FAO protocol for the assessment of food allergens

Questions were raised in relation to the experimental design of the *in vitro* digestibility study on CSPB (Section 4.5.3 of the Safety Assessment Report) and that it was not based on the protocol contained within the 2001 FAO/WHO Expert Consultation report on the *Evaluation of Allergenicity of Genetically Modified Foods*[5]. It is worth noting that this protocol was not adopted by Codex as part of its *Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants* in 2004[6]. Rather, the Codex guideline provides general guidance only in relation to pepsin resistance and also recognises that a number of enzyme susceptibility protocols exist. Alternative protocols may therefore be used where appropriate.

FSANZ assesses all studies on the basis of their scientific merits. The digestibility study submitted in support of the current Application was conducted according to principles of Good Laboratory Practice (GLP) and was certified Quality Assured (QA).
The assessment of digestibility in this Application is entirely consistent with the approach taken by FSANZ for previous GM applications.

As mentioned in Section 10.1.1, the *FSANZ Safety Assessment of Genetically Modified Foods* (see Footnote 1) and the *Application Handbook*[7] are the primary references relevant to GM food safety assessments in Australia and New Zealand. Various protocols and guidelines exist at the international level to assist regulators and industry on the general approach to assessing the toxicity and allergenicity of a range of substances present in food. While these provide guidance on experimental design and interpretation, they do not negate the necessity of sound scientific judgement applied on a case-by-case basis.

9.2.1.8 Additional data on the digestibility of CSPB in simulated intestinal fluid (SIF)

FSANZ has not requested that the Applicant provide another SDS-PAGE image of the digestion of CSPB in SIF because, as described in Sections 4.4.1, 4.5.2 and 4.5.3 of the Safety Assessment Report: (1) There is no evidence in humans of allergenicity arising from exposure to CSPB in *B. subtilis* through ingestion of probiotics; (2). Bioinformatic analyses on CSPB revealed no amino acid sequence similarity with any known protein allergens, and (3) Western blotting indicated that >99% of CSPB was digested in SIF within 5 minutes.. FSANZ is satisfied that undertaking another SDS-PAGE would not provide any useful information in relation to the potential allergenicity of CSPB.

[5] FAO/WHO (2001) Evaluation of allergenicity of genetically modified foods. Available online at ftp://ftp.fao.org/es/esn/food/allergygm.pdf
[6] Codex Alimentarius (2004) Foods derived from biotechnology. Joint FAO/WHO Food Standards Programme. FAO & WHO, Rome. Available online at http://www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf
[7] http://www.foodstandards.gov.au/_srcfiles/Application%20Handbook%20as%20at%2025%20August%202009.pdf

9.2.1.9 Quantification of the background level of dietary exposure to CSPB and CSPB:nucleic acid complexes

As discussed in Section 2.1.1 of the Safety Assessment Report, the source organism of the *cspB* gene, *B. subtilis*, has a safe history of use as a dietary probiotic, animal feed additive, in aquaculture and in the production of traditional foods.

In the Safety Assessment Report, no attempt was made to quantify the background level of dietary exposure to CSPB or CSPB:nucleic acid complexes. MON87460 corn grain contains relatively low levels of CSPB (0.033/0.041 µg/g fresh weight under well watered/water-limited conditions) and therefore the contribution that this would make to total dietary exposure to CSD-containing proteins from all sources would be, qualitatively, negligible. More importantly, there is no evidence that CSPB is intrinsically hazardous (no sequence homology with known toxins or allergens; no acute toxicity; no evidence in the scientific literature that CSD-containing proteins are toxic/allergenic; the source organism is not hazardous and has a history of safe food use) and therefore such a minor incremental increase in exposure presents no safety concerns.

9.2.1.10 Toxicity or allergenicity of CSPB aggregates

It is unclear how such a small quantum of CSPB protein (0.033/0.041 µg/g fresh weight under well watered/water-limited conditions) could possibly aggregate *in vivo* in the presence of so much other material. It is well known for example that the presence of unrelated proteins is a common strategy to prevent proteins from self-aggregating.

9.2.1.11 Characterisation of CSPB from MON87460

A series of technical questions was raised regarding the experiments conducted to establish the equivalence of *E. coli*-derived CSPB to that derived from MON87460 corn (see Section 4.2.1 of the Safety Assessment Report). As CSPB is produced in only small quantities in MON87460 corn, it was necessary to use an alternative means of protein synthesis which resulted in a high yield. CSPB synthesis in genetically modified *E. coli* was chosen because it was able to produce sufficient quantities for further testing in laboratory animals.
This is a standard laboratory procedure where the equivalence of the bacterially-derived protein to the *in planta*-produced protein is established based on the weight-of-evidence from a range of semi-quantitative and qualitative analytical tests. FSANZ is satisfied that the proteins are equivalent on the basis of molecular weight, immunoreactivity, N-terminal sequence, tryptic peptide map, glycosylation status and functional activity.

9.2.1.12 Presence of the nptII gene in MON87460 corn

Given the functional redundancy of the *nptII* gene in MON87460 corn, a suggestion was made that FSANZ should ask the Applicant to remove it. The function *per se* of the *nptII* gene in MON87460 corn is not a relevant consideration for the safety assessment. Based on the absence of detectable levels of NPTII in the edible portion of MON87460 corn (i.e. the grain) and that the safety of NPTII has previously been addressed by FSANZ and others (see Section 4.4.1 of the Safety Assessment Report), the presence of the *nptII* gene is not a concern.

There already exists an extensive body of evidence on NPTII to indicate its presence in food derived from GM crops poses negligible risks to human health. By establishing the equivalence of NPTII in MON87460 corn to the *E. coli*-derived protein, this extensive body of evidence can be utilised. On this basis a more limited analyses was conducted to establish equivalence, which in this context is considered appropriate.

Data submitted by the Applicant and independently evaluated by FSANZ indicated that MON87460-derived NPTII was equivalent to *E. coli*-derived protein on the basis of Western blotting (immunoreactivity) and molecular weight.

9.2.1.13 The single amino acid difference in MON87460-derived CSPB to in the source organism is potentially hazardous to human health

Data evaluated by FSANZ as part of this Application indicated that MON87460-derived CSPB had no biologically-significant amino acid sequence similarity with known or putative protein toxins or allergens, was rapidly degraded *in vitro* and was not toxic to mice. On this basis, CSPB in MON87460 corn is not potentially hazardous to human health.

9.2.1.14 The presence of the 35S promoter from the cauliflower mosaic virus is a potential human health hazard

There is no credible evidence supporting this assertion. Crops containing this promoter element do not facilitate horizontal gene transfer at a rate any higher than exists in non-GM crops. The presence of this or any promoter in a GM crop cannot result in the production of novel human viruses or bacteria.

9.2.1.15 Future findings that may influence an approval decision

Two private submitters were concerned about further GM approvals being made until the findings of the Review of Food Labelling Law and Policy are released, and the findings of research conducted by Dr Judy Carman become publicly available.

The labelling Review committee met for the first time in November 2009 and, as yet, there is no timeline for completion of the Review.

FSANZ has a statutory obligation to consider all applications seeking to amend the *Code*. Further, there is a statutory timeframe associated with this consideration and FSANZ cannot hold up a consideration process on the grounds that information may become available at a future point. In the case of food derived from MON87460 corn, FSANZ considers that sufficient evidence has been provided to allow completion of a safety assessment.

9.2.1.16 The stacking of the cspB gene in MON87460 corn with other GM crops, and dietary exposure to mixtures of GM foods, may cause adverse health effects

Once food derived from a GM crop has been assessed by FSANZ as safe and approval granted, safety concerns do not arise if that food is conventionally bred with any other approved food, GM or non-GM.

9.2.1.17 Statistically significant changes in amino acids and trace minerals in MON87460 corn raise public health and safety concerns

One submitter was concerned at the statistically significant differences in amino acids and trace minerals between MON87460 corn and the conventional control line, DM1718 (noting that both increases and decreases occurred). As discussed in the Safety Assessment Report (Section 5), all of these differences were small in magnitude and within both the 99% tolerance interval (TI) derived from the four reference varieties grown at each field site in addition to the published literature ranges. On this basis, the differences reflect normal biological variation for corn and do not raise safety concerns.

9.2.1.18 Clinical tests should be developed to determine whether people have been exposed to food derived from MON87460 corn or other GM foods

Once FSANZ has determined that food derived from a particular GM crop is as safe and wholesome as its non-GM counterpart varieties, then exposure through the diet does not pose a safety concern. For those who seek to avoid GM foods for any reason, the current GM food labelling laws allow consumers to identify GM products where novel DNA and/or novel protein from an approved GM variety is present in the final food, or if the food has altered characteristics. Some foods, such as oil derived from GM canola are indistinguishable from the non-GM derived oil.

9.2.1.19 Cost-benefit analysis

Two submitters claimed that there was a lack of detail underpinning the cost-benefit analysis, with one of these submitters requesting more data to support it.

The cost-benefit analysis included in the 1st Assessment Report is not intended to be an exhaustive, quantitative dollar analysis of the options and, in fact, most of the impacts that are considered cannot be assigned a dollar value. Rather, the analysis seeks to highlight the qualitative impacts of criteria that are generally relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance and do not, for example, include any consideration of the impact of growing the crop (either to the farmer or to the environment) or intangible costs such as the time consumers spend reading labels.

9.2.1.20 The Application should not be approved until approval is granted in the US. Australian and New Zealand permissions for GM products should be based on broad international permission

While overseas applications or existing approvals are noted, FSANZ's consideration of food derived from GM crops and indeed approval of any food, food additive, or processing aid is conducted independently of the outcome of regulatory processes in other countries. As outlined in (15), FSANZ has a statutory obligation to consider all valid applications seeking to amend the *Code*. In most cases, due to the time periods required to obtain regulatory approval in a number of countries, applicants often seek approvals concurrently. In Australia and New Zealand, the assessment of GM foods generally takes in excess of 12 months to complete.

9.2 World Trade Organization (WTO)

As members of the WTO, Australia and New Zealand are obligated 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.

The inclusion of food derived from MON87460 corn in the Code would have a trade enabling effect as it would permit any foods containing this variety of corn to be imported into Australia and New Zealand and sold, where currently they would be prohibited. For this reason, there was no need to notify this Application under the Sanitary or Phytosanitary Measures (SPS) Agreement.

CONCLUSION

10. Conclusion and Preferred Approach

Preferred Approach

To prepare a draft variation to Standard 1.5.2 – Food produced using Gene Technology, to include food derived from drought-tolerant corn line MON87460 in the Table to clause 2.

10.1 Reasons for Preferred Approach

Proceeding to the development of an amendment to the Code to give approval to the sale and use of food derived from MON87460 corn in Australia and New Zealand is proposed on the basis of the available scientific evidence, for the following reasons:

- the safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce drought-tolerant MON87460 corn
- food derived from MON87460 corn is equivalent to food from the conventional counterpart and other commercially available corn varieties in terms of its safety for human consumption and nutritional adequacy
- labelling of certain foods derived from drought-tolerant MON87460 corn will be required where novel DNA and/or protein is present in the final food
- a regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is Option 2, the development of a food regulatory measure
- 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.

11. Implementation and Review

Following the consultation period for this 2nd Assessment Report, an Approval Report will be completed and the draft variation will be considered for approval by the FSANZ Board. The FSANZ Board's decision will then be notified to the Ministerial Council. Following notification, the proposed draft variation to the Code is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Summary of submissions

Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

To commence: on gazettal

[1] ***Standard 1.5.2*** *of the Australia New Zealand Food Standards Code is varied by inserting in* Column 1 *of the* Table to clause 2 –

Food derived from drought-tolerant corn line MON87460	

Attachment 2

Summary of Public Submission on 1st Assessment Report

Submitter	Comments
New Zealand Food Safety Authority	• Agrees that MON87460 corn can be considered equivalent to conventional corn. • Suggests that the conclusion regarding the unlikely expression of DNA sequences spanning the 5' and 3 insert /corn junction could be strengthened by the analysis of upstream regulatory elements. • Suggests including more detail on the mechanism of drought tolerance in MON87460 corn. • Requests additional detail on the control corn line used as the comparator for the compositional analysis.
Queensland Health (Whole of QLD Govt response)	• Supports approval. • Notes the use of mostly company data to assess the Application. • Considers that the cost-benefit analysis was limited in detail. • Raises the issue of compliance and surveillance costs associated with the approval of this Application.
Australian Food & Grocery Council	• Supports approval on the basis that there is no identified risk to public health & safety. • States that it is up to individuals and companies to make an independent commercial decision whether to use the product.
Michelle Denise (Private)	• Requests that approval be deferred until the outcomes of the Food Labelling Review and the Study by Dr Judy Carman are known.
Shirley Collins (Private)	• Opposes approval. • Requests that there be no more GM crop approvals until the recommendations of the Food Labelling Review are implemented. • Expresses concern at the lack of independent studies on the health effects of GM food. • Notes that the results of Dr Judy Carman study are pending.
Christine Bennett (Private)	• Opposes approval. • Raises the issue of the environmental impact of GM crops, particularly on bees. • Expresses a lack of faith in FSANZ's ability to protect public health & safety.
Paul Elwell-Sutton (Private)	• Opposes approval. • Concerned with the impact of long-term consumption of MON87460 corn on normal cellular ageing processes, neuronal development and memory. • Raises GM labelling issue.

Submitter	Comments
San Diego Tortilla factory (Colin Thomson)	• Opposes approval. • Expresses concern that the long-term health effects of GM foods are unknown. • Expresses concern at the contamination of Australian crops (by MON87460 corn).
David Savill (Private)	• Opposes approval. • Considers that current GM labelling laws are inadequate. • Requests that long-term health studies be conducted by independent scientists. • States that the scientific analysis was conducted by the Applicant and lacks independence.
Ryan Hamilton (Private)	• Opposes approval of all GM applications. • Requests that all GM ingredients are labelled.
GE Free New Zealand (Claire Bleakley)	• Opposes approval. • The following issues were raised: - There is insufficient information for FSANZ to make a decision on the approval of this Application. - FSANZ is not adhering to the requirements of the FSANZ Act by proceeding with the consideration of this Application. - CSPB in MON87460 corn is not equivalent to that of the source organism (*B. subtilis*); the single amino acid difference is potentially hazardous to human health. - The use of bacterially-derived CSPB rather than CSPB from MON87460 corn for the safety studies is inappropriate. - Independent studies conducted over the last 10 years have shown GM foods to be unsafe. - The absence of safety testing on MON87460 corn, including long-term studies or studies conducted according to Codex guidelines and the reliance on company studies. - Transgenes are stable in the digestive tract and are potentially hazardous to human health, especially in sensitive individuals such as the elderly, children, pregnant women and those with underlying medical conditions. - Clinical tests need to be developed to determine whether adverse health effects are attributable to the consumption of GM food. - No data were provided on the potential for the transgene to recombine with microflora in the digestive tract. - There has been a rise in food allergies coincident with the introduction of GM foods. - Increased risk of antibiotic resistance due to the use of antibiotic resistance genes in the development of GM crops. - The presence of the CaMV 35S promoter in MON87460 is a potential hazard to human health because it is inherently unstable and can cause DNA damage.

Submitter	Comments
	- Transgenes carry retroviral fragments and antibiotic resistance genes have been shown to be resistant to digestive processes. - There is no data on the health effects of the stacking of genes in GM crops or dietary exposure to mixtures of GM foods. - Statistically significant changes in amino acid concentrations in MON87460 corn raise health and safety concerns. - GE Free NZ supports the submission by the Centre for Integrated Research in Biosafety submission.
GE Free Northland (S Ajani)	• Opposes approval. • Raises similar issues to GE Free NZ including the following: - The absence of safety testing on MON87460 corn, including long-term studies or studies conducted according to Codex guidelines. - Independent studies conducted over the last 10 years have shown GM foods to be unsafe. - MON87460 corn is hazardous to human health, particularly to sensitive groups in the community such as the elderly, children, pregnant women and those with underlying medical conditions - The lack of diagnostic tools for health practitioners to detect exposure to transgenes. - There has been a rise in food allergies coincident with the introduction of GM foods. - Increased risk of antibiotic resistance due to the use of antibiotic resistance genes in the development of GM crops. - Transgenes carry retroviral fragments and antibiotic resistance genes have been shown to be resistant to digestive processes. - No data on the health effects of stacking of genes in GM crops or dietary exposure to mixtures of GM foods.
Astrid Anderson Zelka Grammer & Tim Vallings Veronica Lawrence Keren Lilburn Julian Pook Melanie Ryder Jen Speedy & Remco Zuiderwijk Brian Tracey Katharine White (Private)	• Opposes approval. • Raises the same issues as those of GE Free Northland.
Soil & Health Association of New Zealand (Steffan Browning)	• Opposes approval. • Raises the same issues as those of GE Free Northland.

Submitter	Comments
Centre for Integrated Research in Biosafety	• Opposes approval unless further information from the Applicant and FSANZ can be provided on the following areas: - The identity of the comparator used in the compositional analysis study. - Evidence for the absence of proteins encoded by novel open reading frames in MON87460 corn. - Evidence for the instability and digestibility of CSPB:nucleic acid complexes when present in whole food. - Confirmation that the protocol used to assess *in vitro* digestibility complies with FAO/WHO standards. - Evidence for the equivalence of CSPB derived from MON87460 corn and *E. Coli* and further explanation on the equivalence criteria used by the Applicant. - Technical information regarding the antibodies used to purify CSPB derived from MON87460 corn and *E. Coli*. - Requests that the *nptII* gene be removed from MON87460 corn as it serves no function. - Evidence that NPTII derived from MON87460 corn and *E. coli* are equivalent in terms of their immunoreactivity. - Additional information and data on the basis for FSANZ's cost benefit analysis.
Member for South Metropolitan Region, WA (Hon Lynn MacLaren MLC)	• Opposes approval of the Application and all GM crops. • Requests that consideration of the approval of all GM Application be deferred until the outcomes of the Food Labelling Review and the Study by Dr Judy Carman study are known. • Considers that the consultation process is not long enough to enable full public participation. • Considers that the biotechnology industry have not demonstrated safe and ethical procedures in relation to human health and the environment. • The following issues were also raised: - The over-reliance on data provided by applicants and that each application should involve independent testing for safety. - Concern about the possible health risks of GM foods, specifically links with allergies, immune and digestive system effects, reduced fertility and accelerated ageing. - Current GM food labelling is inadequate, lags behind European standards and does not allow consumers to make informed choices. - All GM foods should be labelled, including those not containing detectable levels of novel DNA and protein. - Suggests the need for a national surveillance system for possible adverse effects to GM foods.

Submitter	Comments
Food Technology Association of Australia	• Opposes approval of the Application on the basis that approval to grow MON87460 corn has not been granted in the US. • Stated that local permissions for GM products should be based on a broad international permission.