



16 December 2009
[20-09]

APPLICATION A1029

FOOD DERIVED FROM DROUGHT-TOLERANT

CORN LINE MON87460

1st 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 as a Major Procedure and will include two rounds of public consultation.

Safety Assessment

FSANZ has completed a comprehensive safety assessment of food derived from MON87460 corn. 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

Proceed to development of a food regulatory measure, to amend 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 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 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

Public submissions are now invited on this 1st Assessment Report. Comments are requested on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from MON87460 corn.

As this Application is being assessed as a major procedure, there will be two rounds of public comment. Responses to this 1st Assessment Report will be used in development of the Second Assessment Report for the Application.

Invitation for Submissions

FSANZ invites public comment on this Report based on regulation impact principles 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 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 Standards Development 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) 10 February 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
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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: Application A1029 – Food Derived from Drought-Tolerant Corn Line MON87460

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.

This Assessment includes a full scientific evaluation of food derived from MON87460 corn according to FSANZ guidelines¹ to assess its safety for human consumption. Public comment is now sought on the safety assessment and proposed recommendations prior to further consideration and completion of the Application.

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 as a Major Procedure.

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

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.

4. Questions for first assessment

Based on information provided by the Applicant on the nature of the genetic modification, the molecular characterisation, the characterisation of the novel proteins, the compositional analysis and consideration of any nutritional issues, is food derived from MON87460 corn comparable to food derived from conventional varieties of corn in terms of its safety for human consumption?

Is other information available, including from the scientific literature, general technical information, independent scientists, other regulatory agencies and international bodies, and the general community, that should be taken into account in this assessment?

Are there any other considerations that would influence the outcome of this assessment?

RISK ASSESSMENT

Food derived from drought-tolerant MON87460 corn has been evaluated according to the safety assessment guidelines prepared by FSANZ² and is provided in **Supporting Document 1**. The summary and conclusions from the safety assessment are presented below.

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.

5. Risk Assessment Summary

5.1 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.

5.2 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.

² FSANZ (2007) Safety Assessment of Genetically Modified Foods – Guidance Document. http://www.foodstandards.gov.au/srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf

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.

5.3 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

6. Issues raised

6.1 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.

7. Options

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

7.1 Option 1 – Maintain the *status quo*

Maintain the *status quo* by rejecting the Application.

7.2 Option 2 – Proceed to the development of a food regulatory measure

Proceed to development of a food regulatory measure to amend Standard 1.5.2 to permit the sale and use of food derived from dual herbicide-tolerant drought-tolerant MON87460 corn, with or without specified conditions in the Table to clause 2 of the Standard.

8. 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.

8.1 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.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – prohibit food from MON87460 corn

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.

8.2.2 Option 2 – approve food from MON87460 corn

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.

8.3 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

9. Communication

FSANZ has applied a 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 Assessment Report will be available to the public on the FSANZ website and distributed to major stakeholders. Public comments on this Assessment will be used in preparing the Second Assessment that may include the development of a draft variation to the Code. Following a second round of public consultation, an Approval Report will be completed and the draft variation will be considered for approval 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.

10. Consultation

Public submissions are invited on this 1st Assessment Report. Comments are 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 are also invited.

As this Application is being assessed as a major procedure, there will be two rounds of public comment. Responses to this 1st Assessment Report will be taken into consideration in developing the Second Assessment Report for the Application.

10.1 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.

This issue will be fully considered at 2nd Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (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.

CONCLUSION

11. Conclusion and Preferred Approach

Preferred Approach

Proceed to development of a food regulatory measure, to amend 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.

11.1 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.

12. Implementation and Review

Following the consultation period for this document, a Second Assessment Report will be prepared that includes a draft variation to the Code. Following a second round of public consultation, 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.