

7 April 2010 [9-10]

APPLICATION A1035 FOOD DERIVED FROM INSECT-PROTECTED SOYBEAN LINE MON 87701 ASSESSMENT REPORT

Executive Summary

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Ltd (the Applicant) on 27 August 2009. The Applicant has requested an amendment to the *Australia New Zealand Food Standards Code* (the Code), specifically to Standard 1.5.2 – Food produced using Gene Technology, to permit the sale and use of food derived from a new genetically modified (GM) variety of soybean, MON 87701. Standard 1.5.2 requires that GM foods undergo a pre-market safety assessment before they may be sold in Australia and New Zealand.

Soybean MON 87701has been genetically modified to be protected against feeding damage caused by the larvae of certain insect pest species. Protection is achieved through expression in the plant of an insecticidal protein derived from *Bacillus thuringiensis*, a common soil bacterium.

Soybean line MON 87701 is intended to be grown in South America. However, once commercialised, soybean products imported into Australia and New Zealand could contain ingredients derived from MON 87701. Approval is therefore necessary before these products may enter the Australian and New Zealand markets.

The Application is being assessed under the General Procedure.

Safety Assessment

FSANZ has completed a comprehensive safety assessment of food derived from insectprotected soybean line MON 87701, as required under Standard 1.5.2. The 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 MON 87701 soybean compared with that of conventional soybean 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 insect-protected soybean line MON 87701 is considered as safe and wholesome as food derived from other commercial soybean varieties.

Labelling

If approved, food derived from insect-protected soybean line MON 87701 will be required to be labelled as genetically modified if novel DNA and/or novel protein is present in the final food. Studies conducted by the Applicant show that the novel proteins are present in the seed.

Labelling addresses the objective set out in section 18(1)(b) of the Food Standards Australia New Zealand Act 1991 (FSANZ Act); the provision of adequate information relating to food to enable consumers to make informed choices.

Impact of regulatory options

Two regulatory options were considered in the assessment: (1) no approval; or (2) approval of food derived from insect-protected soybean line MON 87701 based on the conclusions of the safety assessment.

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

Assessing the Application

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the FSANZ Act:

- Whether costs that would arise from an amendment to the Code approving food derived from insect-protected soybean line MON 87701 outweigh the direct and indirect benefits to the community, Government or industry that would arise from this 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.
- There are no 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 insect-protected soybean line MON 87701 in the Table to clause 2.

Reasons for Preferred Approach

An amendment to the Code approving food derived from insect-protected soybean line MON 87701 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 insect-protected soybean line MON 87701
- food derived from insect-protected soybean line MON 87701 is equivalent to food from the conventional counterpart and other commercially available soybean varieties in terms of its safety for human consumption and nutritional adequacy
- labelling of certain foods derived from insect-protected soybean line MON 87701 will be required if novel DNA and/or protein is present in the final food
- a regulation impact assessment process has been undertaken that also fulfils the requirement in 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 Assessment Report. Comments are specifically requested on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food from insect-protected soybean MON 87701.

As this Application is being assessed as a general procedure, there will be one round of public comment. Responses to this Assessment Report will be used to develop the Approval Report for the Application.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variation to the Code 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/Proposal. 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 <u>Changing the Code</u> tab and then through <u>Documents for Public Comment</u>. Alternatively, you may email your submission directly to the Standards Management Officer at <u>submissions@foodstandards.gov.au</u>. 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: 19 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) 473 9942

INTRODUCTION	2
 THE ISSUE / PROBLEM	2 2 2 3
RISK ASSESSMENT	3
 5. RISK ASSESSMENT SUMMARY	4 4
RISK MANAGEMENT	5
 6. OPTIONS 6.1 Option 1 – Prohibit food from soybean line MON 87701 6.2 Option 2 – Approve food from soybean line MON 87701 7. IMPACT ANALYSIS 7.1 Affected Parties 7.2 Benefit Cost Analysis 7.3 Comparison of Options 	5 5 5 5 6
COMMUNICATION AND CONSULTATION STRATEGY	7
8. Communication 9. Consultation	8
CONCLUSION	8
 10. CONCLUSION AND PREFERRED APPROACH	8 9 E

CONTENTS

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/foodstandards/applications/applicationa1029food4367.cfm

SD1: Safety Assessment Report AMENDED

INTRODUCTION

An Application was received from Monsanto Australia Ltd on 27 August 2009 seeking an amendment to Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code), to approve food derived from insect-protected soybean line MON 87701.

The genetic modification involved the transfer of one novel gene into soybean. This gene is from a common soil bacterium called *Bacillus thuringiensis* and encodes an insecticidal protein (Cry1Ac) which protects the plant against feeding damage caused by certain insect pest larvae. No antibiotic resistance marker genes are present in MON 87701 soybean.

This Assessment includes a full scientific evaluation of food derived from MON 87701 soybean 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 soybean line MON 87701 that is protected from feeding damage caused by certain lepidopteran insect pest larvae. Before food derived from insect-protected soybean line MON 87701 can enter the Australian and New Zealand food supply, it must first be assessed for safety and an amendment to the Code must be approved by the FSANZ Board, and subsequently be notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). An amendment to the Code may only be gazetted once the Ministerial Council process has been finalised.

Monsanto Australia Ltd has therefore applied to have Standard 1.5.2 amended to include food derived from soybean line MON 87701. The Application is at the Assessment stage.

2. Current Standard

2.1 Background

Standard 1.5.2 requires that genetically modified foods undergo a pre-market safety assessment before they may be sold in Australia and New Zealand. Foods that have been assessed under the Standard, if approved, are listed in the Table to clause 2 of the Standard.

2.2 Overseas approvals

Insect-protected soybean line MON 87701 is intended for commercialisation in South America. The applicant has submitted a food and feed safety and nutritional assessment summary to the US Food and Drug Administration and a request for a determination of nonregulated status from the US Department of Agriculture. Food, feed and environmental submissions were made to the Canadian Food Inspection Authority, Health Canada and a cultivation submission was made to Brazilian National Biosafety Technical Commission . The applicant also applied to the European Food Safety Authority for food and feed use of imported MON 87701.

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

Regulatory submissions have been or will be made to significant importers of soybean or processed soybean fractions. These include the Ministry of Agriculture in China, the Ministry of Health, Labor and Welfare and the Ministry of Agriculture, Forestry and Fisheries in Japan, as well as the Food and Drug Administration and the Rural Development Administration in the Republic of Korea.

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 to be answered

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 any nutritional issues, is food derived from soybean line MON 87701 comparable to food derived from conventional varieties of soybean in terms of its safety for human consumption?

Is there other information available, including from the scientific literature, general technical information, independent scientists, other regulatory agencies and international bodies, and the general community, that needs to be considered?

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

RISK ASSESSMENT

Food from insect-protected soybean line MON 87701 has been evaluated according to the safety assessment guidelines prepared by FSANZ. The summary and conclusions from the full safety assessment report (Supporting Document 1²) are presented below.

² <u>http://www.foodstandards.gov.au/foodstandards/applications/applicationa1029food4367.cfm</u>

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

5. Risk Assessment Summary

5.1 Safety Assessment Process

In conducting a safety assessment of food derived from insect-protected MON 87701 soybean, a number of criteria have been addressed including: a characterisation of the transferred genes, their origin, function and stability in the soybean genome; the changes at the level of DNA, protein and in the whole food; 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 soybean line MON 87701 addresses only food safety and nutritional issues. It therefore does not address: environmental risks related to the environmental release of genetically modified (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

Detailed molecular analyses indicate that one copy of the *cry1Ac* gene has been inserted at a single site in the plant genome and the gene is stably inherited from one generation to the next. No antibiotic resistance marker genes are present in MON 87701 soybean.

MON 87701 expresses one novel protein, Cry1Ac. The Cry1Ac protein is expressed at low levels in the soybean seed, with a mean concentration of 4.2 μ g/g fresh weight.

The Cry1Ac protein is >99% identical to the native Cry1Ac protein from *B. thuringiensis* subsp *kurstaki*, differing by seven amino acids. However, the Cry1Ac sequence from MON 87701 is 100% identical to that in cotton lines, MON 1849 and 15895, which have previously been approved by FSANZ for food use. In addition, there is a four amino acid addition at the N-terminus of the protein that serves to target it to the chloroplast. This N-terminal tag is cleaved from the protein during prototoxin activation.

A large number of studies have been done with Cry1Ac expressed in MON 87701 to confirm its identity and physicochemical and functional properties as well as to determine its potential toxicity and allergenicity. These studies have demonstrated that the protein conforms in size and amino acid sequence to that expected, does not exhibit any post-translational modification including glycosylation, and demonstrates the predicted insecticidal activity.

In relation to potential toxicity and allergenicity, *B. thuringiensis* has been extensively studied and has a long history of safe use as the active ingredient in a number of insecticide products for use in agriculture as well as home gardens.

Bioinformatic studies with the Cry1Ac protein have confirmed the absence of any biologically significant amino acid sequence similarity to known protein toxins or allergens and digestibility studies have demonstrated that the protein would be rapidly degraded following ingestion, similar to other dietary proteins. Acute oral toxicity studies in mice with the Cry1Ac protein have also confirmed the absence of toxicity. Taken together, the evidence indicates that both proteins are unlikely to be toxic or allergenic in humans.

Compositional analyses were done to establish the nutritional adequacy of MON 87701 soybean, and to compare it to conventional soybean under typical cultivation conditions. No differences of biological significance were observed between MON 87701 soybean and its conventional counterpart. Food from insect-protected MON 87701 soybean is therefore considered to be compositionally equivalent to food from conventional soybean varieties and its introduction into the food supply would therefore be expected to have little nutritional impact.

As soybean is one of the major allergenic foods, the allergenicity of MON 87701 was compared to that of several commercial soybean varieties by assessing IgE binding responses using sera from known soybean allergic patients. Sera from these patients bound to MON87701 in a very similar manner to that of conventional soybean, suggesting that MON87701 does not have any greater potential to be allergenic than conventional soybean varieties.

5.3 Conclusions

No potential public health and safety concerns have been identified in the assessment of insectprotected MON 87701 soybean. On the basis of the data provided in the present application, and other available information, food derived from insect-protected MON 87701 soybean is considered as safe and wholesome as food derived from conventional soybean varieties.

RISK MANAGEMENT

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 to approve food derived from insectprotected soybean line MON 87701.

6.2 Option 2 – Prepare a draft variation for food from soybean line MON 87701

Prepare draft variations to amend Standard 1.5.2 of the Code to permit the sale and use of food derived from insect-protected soybean line MON 87701, with or without specified conditions in the Table to clause 2 of the Standard.

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 food products containing soybean, particularly those concerned about biotechnology.

- Industry sectors:
 - food importers and distributors of wholesale ingredients
 - processors and manufacturers of food products containing soybean
 - food retailers.
- Government:
 - enforcement agencies
 - national government, in terms of trade and World Trade Organization (WTO) obligations.

The cultivation of soybean line MON 87701 in Australia or New Zealand could have an impact on the environment, which would need to be assessed by the Office of the Gene Technology Regulator (OGTR) in Australia, and by various New Zealand government agencies including the Environmental Risk Management Authority (ERMA) and the Ministry of Agriculture and Forestry (MAF) before growing in either country could be permitted. MON 87701 soybean has been developed primarily for agricultural production overseas and, at this stage, the Applicant has no plans for cultivation in either Australia or New Zealand.

7.2 Benefit Cost Analysis

- 7.2.1 Option 1 prohibit food from soybean line MON 87701
- <u>Consumers:</u> Possible restriction in the availability of soybean products if MON 87701 soybean is present in imported foods.

No impact on consumers wishing to avoid GM foods, as food from MON 87701 soybean is not currently permitted in the food supply.

- <u>Government:</u> 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 soybean imports once MON 87701 soybean 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 approve food from soybean line MON 87701
- <u>Consumers:</u> Broader availability of imported soybean products as there would be no restriction on imported soybean products derived from MON 87701 soybean.

Potentially a wider range of imported soybean products at lower prices.

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

<u>Government:</u> Benefit that if MON 87701 soybean were detected in soybean imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of MON 87701 soybean would ensure no conflict with WTO responsibilities.

This option could impact on monitoring resources, as certain foods derived from MON 87701 soybean will be required to be labelled as genetically modified.

Industry: Food manufacturers gain broader market access and increased choice in raw materials.

Importers of processed foods containing soybean as an ingredient would benefit as foods derived from MON 87701 soybean would be compliant with the Code.

Retailers may be able to offer a broader range of soybean products.

Possible cost to food industry as some food ingredients derived from MON 87701 soybean would be required to be labelled as genetically modified.

7.3 Comparison of Options

As food from insect-protected soybean line MON 87701 has been found to be as safe as food from conventional varieties of soybean, 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 wishing to avoid GM foods, as approval of MON 87701 soybean by other countries could limit supplementation of the Australian and New Zealand market with imported soybean products.

As MON 87701 soybean has been found to be safe for human consumption and the potential benefits outweigh the potential costs, Option 2, preparing draft legislation to approve insect-protected soybean line MON 87701, is therefore the preferred option.

COMMUNICATION AND CONSULTATION STRATEGY

8. 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 comment on this Assessment will be sought prior to preparation of the Approval Report.

The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the Application. After the FSANZ Board has considered the Approval Report, if the draft variation to the Code is approved, we will notify that decision to the Ministerial Council. If the approval of food derived from insect-protected soybean line MON 87701 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. In addition, FSANZ provides an advisory service to the jurisdictions on changes to the Code.

9. Consultation

9.1 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 draft variation to the Code would have a trade enabling effect as it would permit food derived from MON 87701 soybean to be imported into Australia and New Zealand and sold, where currently it is prohibited. For this reason it was determined there is no need to notify this Application as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Agreement on the Application of SPS Measures.

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 insect-protected soybean line MON 87701 in the Table to clause 2.

10.1 Reasons for Preferred Approach

An amendment to the Code to give approval to the sale and use of food derived from soybean line MON 87701 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 insect-protected soybean line MON 87701
- food derived from insect-protected soybean line MON 87701 is equivalent to food from the conventional counterpart and other commercially available soybean varieties in terms of its safety for human consumption and nutritional adequacy
- labelling of certain foods derived from insect-protected soybean line MON 87701 will be required if novel DNA and/or protein is present in the final food
- a regulation impact assessment process has been undertaken that also fulfils the requirement in 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.

11. Implementation and Review

Following the consultation period for this document, 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 variation to the Australia New Zealand Food Standards Code

Attachment 1

Draft variation to the Australia New Zealand Food Standards Code

Subsection 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 –

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Food derived from insect-protected soybean line	
MONIOZZOA	
MON 87701	