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

18 October 2011
[19-11]

APPLICATION A1063
FOOD DERIVED FROM HERBICIDE-TOLERANT SOYBEAN LINE MON87708
ASSESSMENT REPORT

EXECUTIVE SUMMARY

Main points are:

- **The Application seeks approval for food derived from a genetically modified (GM), herbicide-tolerant soybean line.**
- **The Safety Assessment did not identify any potential public health and safety concerns.**
- **This Report recommends the preparation of a draft variation to the Code to include food derived from soybean line MON87708 in Standard 1.5.2.**
- **At present, there is no approval to grow this GM soybean line in Australia or New Zealand. Food derived from it would therefore enter the food supply through imported products.**
- **In accordance with the labelling laws, food derived from this GM soybean line would have to be labelled as GM if it contains novel DNA or novel protein.**

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Limited (Monsanto) on 27 May 2011. The Applicant requested a variation 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 genetically modified (GM) soybean line MON87708, conferring herbicide-tolerance.

This Application is being assessed under the General Procedure and will include one round of public consultation.

Safety Assessment

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in s 18 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), is the protection of public health and safety. Accordingly, the safety assessment forms the central component in considering an application.

A new genetically modified (GM) soybean line, MON87708, is tolerant to the herbicide dicamba.

Tolerance to dicamba is achieved through expression of dicamba mono-oxygenase (DMO) encoded by the *dmo* gene derived from the soil bacterium *Stenotrophomonas maltophilia*.

FSANZ has completed a comprehensive safety assessment of food derived from soybean line MON87708 (see **Supporting Document 1**). 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 soybean line MON87708 compared with that of conventional soybean cultivars. No public health and safety concerns have been identified in this assessment.

On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from soybean line MON87708 is considered as safe and wholesome as food derived from other commercial soybean cultivars.

Other assessment considerations

In assessing the Application, FSANZ has had regard to the following matters as prescribed in s 29 of the FSANZ Act, in addition to considering the safety of food derived from soybean line MON87708:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure

- whether there are other measures that would be more cost-effective than a variation to Standard 1.5.2 and could achieve the same end

- any relevant New Zealand standards

- any other relevant matters.

Labelling

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.

In accordance with general labelling provisions, food derived from soybean line MON87708, if approved, would be required to be labelled as genetically modified if novel DNA or novel protein is present in the final food.

Preferred Approach

To prepare a draft variation to Standard 1.5.2 - Food produced using Gene Technology, to include food derived from herbicide-tolerant soybean line MON87708 in the Schedule.

Reasons for Preferred Approach

On the basis of the available evidence, the development of a draft variation to the Code to give approval to the sale and use of food derived from herbicide-tolerant soybean line

MON87708 in Australia and New Zealand is proposed, for the following reasons:

- The Safety Assessment did not identify any public health and safety concerns associated with the genetic modification used to produce soybean line MON87708.

- Food derived from soybean line MON87708 is equivalent to that derived from the conventional counterpart and other commercially available soybean cultivars in terms of its safety for human consumption and nutritional adequacy.

- Labelling of food derived from soybean line MON87708 will be required in the ingredients list or in conjunction with the name of the food, if it contains novel DNA or novel protein.

- Two regulatory options were considered: (1) rejection of the Application; or (2) approval of food derived from soybean line MON87708. 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.

- 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 and could achieve the same end.

Consultation

Public submissions are now invited on this Assessment Report. Comments are requested on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from soybean line MON87708.

As this Application is being assessed under a General Procedure, there will be one round of public comment. Responses to this Assessment Report will be considered in the Approval Report for the Application.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations 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 s 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) 29 November 2011

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 6143
NEW ZEALAND
Tel (04) 978 5630

CONTENTS

SUPPORTING DOCUMENT

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/applicationa1063food5198.cfm

SD1: Safety Assessment Report: Application A1063 – Food Derived from Herbicide-Tolerant Soybean Line MON87708

INTRODUCTION

On 27 May 2011, Monsanto Australian Limited (Monsanto) submitted an Application seeking approval for food derived from soybean line MON87708 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

Soybean line MON87708 is tolerant to the herbicide dicamba. Tolerance to dicamba is achieved through the introduction of the *dmo* gene, from the soil bacterium *Stenotrophomonas maltophilia*, expressing the protein dicamba mono-oxygenase (DMO). DMO rapidly demethylates dicamba to a non-herbicidal metabolite, thereby allowing the plant to remain functional in the presence of dicamba. FSANZ has not previously assessed this protein.

The purpose of the genetic modification is to provide soybean growers with a broader weed control option.

This Assessment includes a full scientific evaluation of food derived from soybean line MON87708 according to FSANZ guidelines (FSANZ, 2007) 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 GM soybean line MON87708. Pre-market approval is necessary before food product derived from this line may enter the Australian and New Zealand food supply. A variation to the Code granting approval to food derived from soybean line MON87708 must be approved by the FSANZ Board, and subsequently notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). A variation to the Code may only be gazetted once the Ministerial Council process has been finalised.

Soybean line MON87708 is intended for cultivation in major soybean-growing countries. Before its release into commercial markets, the Applicant is seeking regulatory approval for the line in a number of trading markets, including Australia and New Zealand. This is necessary because, once it is cultivated on a commercial-scale, processed soybean products imported into Australia and New Zealand could contain components derived from soybean line MON87708. The Application is being assessed as a General 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 Schedule to the Standard.

2.2 Overseas approvals

Monsanto submitted a food and feed safety and nutritional assessment summary for MON87708 to the United States Food and Drug Administration in November 2010 and also requested a Determination of Nonregulated Status for MON 87708, including all progeny derived from crosses between MON 87708 and other soybean, from the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture in July 2010.

Applications have also been submitted to the Canadian Food Inspection Agency and Health Canada in November 2010, the European Food Safety Authority in January 2011, Korean Food and Drug Administration for food use in February 2011, and Rural Development Administration for feed use in February 2011, and Japan's Ministry of Health, Labour, and Welfare for food use in March 2011.

Submissions are likely to be made to a number of additional governmental regulatory agencies including Ministry of Agriculture, People's Republic of China; Japan's Ministry of Agriculture, Forestry, and Fisheries; and the Intersectoral Commission for Biosafety of Genetically Modified Organisms, Mexico.

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 s 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

In completing the Assessment of this Application, the following questions were addressed:

- 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 soybean line MON87708 comparable to food derived from conventional cultivars of soybean 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 soybean line MON87708 has been assessed according to the safety assessment guidelines prepared by FSANZ (2007). The full Safety Assessment 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

The Safety Assessment of soybean line MON87708 included the following key elements: 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; 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 assessment of soybean line MON87708 was restricted to food safety and nutritional issues. Any risks related to the release into the environment of GM plants used in food production, the safety of animal feed, or animals consuming feed derived from GM plants, or the safety of food derived from the non-GM (conventional) plant have not been addressed in this assessment.

5.2 Outcomes of the Safety Assessment

Soybean cultivar A3525 was transformed with two gene expression cassettes using an *Agrobacterium*-mediated method. The first cassette contained the *dmo* gene while the second cassette contained, as a marker, the commonly used *cp4 epsps* gene that confers tolerance to the herbicide glyphosate.

Comprehensive molecular analyses of soybean line MON87708 indicate there is a single insertion site comprising a complete copy of the *dmo* expression cassette. The second expression cassette containing the *cp4epsps* gene, that was used in the initial transformation, was deliberately segregated out and so is absent from MON87708.

The introduced genetic elements are stably inherited from one generation to the next. There are no antibiotic resistance marker genes present in the line and plasmid backbone analysis shows that no plasmid backbone has been incorporated into the transgenic locus.

Soybean line MON87708 expresses one novel protein that can be present as a mixture of two monomers comprising the mature DMO and the DMO precursor protein. Both DMO monomers are functional.
Total DMO (comprising both monomers) was detected in all parts that were analysed, being lowest in the root (approximately 6 µg/g dry weight) and highest in older leaves (approximately 70 µg/g dry weight). The seed contained approximately 47 µg/g dry weight.

Several studies were done to confirm the identity and physicochemical properties of the DMO protein expressed in MON87708 and demonstrated that the monomers conform in size and amino acid sequence to that expected, and do not exhibit any post-translational

modification including glycosylation.

Bioinformatic studies have confirmed the lack of any significant amino acid sequence similarity to known protein toxins or allergens and digestibility studies have demonstrated that both monomers would be completely digested before absorption in the gastrointestinal tract would occur. As anticipated a mouse oral toxicity study revealed no treatment-related effects.. It was further demonstrated that the MON88708 DMO protein is not stable at elevated temperatures and loses most of its activity above 55^{o} C. Taken together, the evidence indicates that DMO is unlikely to be toxic or allergenic to humans.

The residues generated on soybean line MON87708 as a result of spraying with dicamba are the same as those found on conventional crops sprayed with dicamba. Residue data derived from supervised trials indicate that the residue levels in seed are low and that there is some concentration of residue in hulls, toasted defatted meal and defatted flour but not in other processed commodities. In the absence of any significant exposure to either parent herbicide or metabolites the risk to public health and safety is negligible.

Detailed compositional analyses were done to establish the nutritional adequacy of seed from soybean line MON87708 sprayed with dicamba. Analyses were done of 57 analytes encompassing proximates, fibre, fatty acids, amino acids, isoflavones, anti-nutrients and vitamin E. The levels were compared to levels in the seeds of the non-GM parent A3525.

These analyses indicated that the seeds of soybean line MON87708 are compositionally equivalent to those of the parental line. Out of the analytes tested, there were significant differences between the non-GM control and soybean MON87708 in 27 analytes. In all of these, except for behenic acid, the mean levels observed in seeds of soybean MON87708 were within the range of natural variation either reported in the literature or derived from 18 non-GM commercial varieties grown in the same field trials. For any analyte, the magnitude of the differences observed between MON87708 and A3525 was not as great as the magnitude between the reference varieties.

In addition, no difference between seeds of soybean line MON87708 and A3525 were found in an IgE binding study using sera from soybean-allergic individuals.

The compositional data are consistent with the conclusion that there are no biologically significant differences in the levels of key components in seed from soybean line MON87708 when compared with the non-GM control or with the range of levels found in non-GM commercial soybean cultivars.

Conclusion

No potential public health and safety concerns have been identified in the assessment of soybean line MON87708. On the basis of the data provided in the present Application, and other available information, food derived from soybean line MON87708 is considered as safe for human consumption as food derived from conventional soybean cultivars.

RISK MANAGEMENT

6. Issues

6.1 Labelling

In accordance with general labelling provisions, food derived from soybean line MON87708, if approved, would be required to be labelled as genetically modified if it contains novel DNA or novel protein.

Soybean MON87708 is intended primarily for use as a broad-acre commodity (field soybean) to produce products derived from cracked soybeans, and is not intended for vegetable or garden purposes where food-grade products may include tofu, soybean sprouts, soy milk, and green soybean (e.g. edamame). This latter type of soybean generally has a different size, flavour and texture to field soybean. The main food product from field soybean is refined oil in which, because of the production process, protein and DNA are not likely to be present and therefore the oil is unlikely to require labelling. Other products such as protein concentrate, protein isolate and textured flour are likely to contain protein and DNA and if so, would require labelling.

6.2 Detection Methodology

Recently, the Implementation Sub-Committee (ISC), a sub-committee of the Food Regulation Standing Committee, agreed to the formation of an Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions, that would identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM applications. As part of its remit, the EAG will make recommendations to Australian and New Zealand enforcement agencies on suitable methods of analysis. To date this EAG has not yet been formed but, as part of an application, the Applicant is required to confirm there is a method of analysis that is fit-for-purpose.

For soybean line MON87708, this methodology involves the use of the polymerase chain reaction for DNA detection. Because of the technology involved, this detection method is likely to be restricted to specialist laboratories.

Since Monsanto has also submitted an application to EFSA, there is a requirement, under Regulation (EC) No 1829/2003 of the European Parliament, for an event-specific detection methodology to be supplied for assessment and validation by the European Union Reference Laboratory for GMOs in Food and Feed. Once validated, this methodology is published by the European Commission Joint Research Centre on its GMO Detection Methods database (http://gmo-crl.jrc.ec.europa.eu/gmomethods/).

7. Impact Analysis

The impact analysis represents likely impacts based on available information. The impact analysis is designed to assist in the process of identifying the affected parties, any alternative options consistent with the objective of the proposed changes, and the potential impacts of any regulatory or non-regulatory options. The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010 (reference 12065) provided an exemption from the need of the OBPR to be informed about GM food applications made to FSANZ.

There were no non-regulatory options for this Application. Two regulatory options, as follows, were available for consideration following the assessment:

Option 1 – Reject application

Reject the Application, thus maintaining the *status quo*.

Option 2 – Prepare a draft variation

Prepare a draft variation to Standard 1.5.2 to permit the sale and use of food derived from soybean line MON87708.

7.1 Affected Parties

The affected parties may include the following:

- Consumers of soybean-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 soybean-containing food products
  - food retailers.

- Government:

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

It is the Applicant's intention that soybean line MON87708 be commercially cultivated in major soybean-producing countries. There is currently no intention to apply for approval to cultivate this variety in either Australia or New Zealand. Such cultivation 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 the Environmental Protection Authority (EPA) in New Zealand, before commercial release in either country could be permitted.

7.2 Benefit Cost Analysis

FSANZ has a statutory obligation under s 29 of the FSANZ Act to consider the cost/benefit of both options. This 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 relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

7.2.1 Option 1 – Reject Application

Consumers: Possible restriction in the availability of imported soybean products to those products that do not contain soybean line MON87708.

No impact on consumers wishing to avoid GM foods, as food from soybean line MON87708 is not currently permitted in the food supply.

Potential increase in price of imported soybean foods due to requirement for segregation of soybean line MON87708.

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 soybean food products if soybean line MON87708 were to be commercialised overseas.

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

7.2.2 Option 2 – Develop a draft regulatory measure

Consumers: Broader availability of imported soybean products as there would be no restriction on imported foods containing soybean line MON87708.

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

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

Government: Benefit that if soybean line MON87708 was 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 soybean line MON87708 would ensure no conflict with WTO responsibilities.

In the case of approved GM foods, monitoring is required to ensure compliance with the labelling requirements, and in the case of GM foods that have not been approved, monitoring is required to ensure they are not illegally entering the food supply. The costs of monitoring are thus expected to be comparable, whether a GM food is approved or not.

Industry: Importers of processed foods containing soybean derivatives would benefit as foods derived from soybean line MON87708 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 soybean products or imported foods manufactured using soybean derivatives.

Possible cost to food industry as some food ingredients derived from soybean line MON87708 would be required to be labelled.

7.3 Comparison of Options

As food from soybean line MON87708 has been found to be as safe as food from conventional cultivars 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, as approval of soybean line MON87708 by other countries could limit the availability of imported soybean products in the Australian and New Zealand markets.

In addition, Option 1 would result in the requirement for segregation of any products containing soybean line MON87708 from those containing approved soybean lines which would be likely to increase the costs of imported soybean foods.

Based on the conclusions of the Safety Assessment, the potential benefits of Option 2 outweigh the potential costs. A variation to Standard 1.5.2 giving approval to herbicide tolerant soybean line MON87708 was therefore the preferred option.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

FSANZ has developed and will apply a basic communication strategy to this Application. The strategy involves notifying subscribers and any interested parties of the availability of the Assessment Reports for public comment and placing the reports on the FSANZ website.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the application and the impacts of regulatory options.

The issues raised in the public submissions will be evaluated and taken into account by the FSANZ Board in its final decision.

Since 1 May 2011, FSANZ has been placing all new applications on the FSANZ website. Over time applications received before 1 May 2011, particularly those that have attracted public interest will be added to the website. The dossier for A1063 is already available on the website at
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1063food5198.cfm

The draft variation will be considered for approval by the FSANZ Board taking into consideration public comments received on this Assessment Report.

The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the assessment. If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to Council. If the decision to approve food derived from herbicide-tolerant soybean line MON87708 is not subject to review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the website.

10. Consultation

Public submissions are invited on this Assessment Report. Comments are specifically sought on the draft variation and scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from herbicide-tolerant soybean line MON87708.

10.1 World Trade Organization (WTO)

As members of the World Trade Organization (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 herbicide-tolerant soybean line MON87708 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

11. Conclusion and Preferred Option

Preferred Approach

To prepare a draft variation to Standard 1.5.2 - Food produced using Gene Technology, to include food derived from herbicide-tolerant soybean line MON87708 in the Schedule.

11.1 Reasons for Preferred Approach

The development of a variation to the Code to give approval to the sale and use of food derived from herbicide-tolerant soybean line MON87708 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 soybean line MON87708.
- Food derived from soybean line MON87708 is equivalent to that derived from the conventional counterpart and other commercially available soybean cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of food derived from soybean line MON87708 will be required in the ingredients list or in conjunction with the name of the food, if it contains novel DNA or novel protein.
- Two regulatory options were considered: (1) rejection of the Application; or (2) approval of food derived from soybean line MON87708. 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.
- 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 and could achieve the same end.

12. 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. If approved, the draft variation will take effect on Gazettal.

REFERENCES

FSANZ (2007) *Safety Assessment of Genetically Modified Foods – Guidance Document*. Document prepared by Food Standards Australia New Zealand. http://www.foodstandards.gov.au/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf.

ATTACHMENTS

1. Draft Variation to the *Australia New Zealand Food Standards Code*
2. Draft Explanatory Statement

Attachment 1

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

Food Standards (Application A1063 – Food derived from Herbicide-tolerant Soybean MON87708) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated XXXX

[Signature to be inserted]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Application A1063 – Food derived from Herbicide-tolerant Soybean MON87708) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

This variation commences **on the date of gazettal**.

SCHEDULE

[1] ***Standard 1.5.2*** *is varied by inserting in numerical order in the* Schedule –

	7.x	Food derived from herbicide-tolerant soybean line MON87708	

Attachment 2

Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).`

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1063 which seeks permission for the sale and use of food derived from herbicide-tolerant soybean line MON8770. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to the Standard for public comment.

2. Purpose and operation

As it is not listed in the Schedule to Standard 1.5.2, food derived from soybean line MON87708 is not currently permitted for sale or use in food. Therefore, FSANZ is proposing to vary Standard 1.5.2 by including food derived from soybean line MON87708 in the Schedule.

3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1063 includes one round of public consultation following an assessment and the preparation of a draft variation. A Report (which includes the draft Standard) was released for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the use of food derived from soybean line MON87708, if approved, would be voluntary and would be likely to have a minor impact on business and individuals.

5. Variation

5.1 Item [1]

This item adds food derived from soybean line MON87708 into the Schedule to Standard 1.5.2.