



14 February 2011
[3-11]

APPLICATION A1046 FOOD DERIVED FROM HERBICIDE-TOLERANT SOYBEAN LINE DAS-68416-4 1st 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 proceeding to the development of a variation to the Code to include food derived from soybean line DAS-68416-4 in Standard 1.5.2.**
- **At present, there is no approval to grow this GM soybean line in Australia. Food derived from it would therefore enter the food supply of Australia and New Zealand 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 Dow AgroSciences Australia Limited (Dow) on 5 May 2010. 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 DAS-68416-4, conferring herbicide-tolerance.

This Application is being assessed under the Major Procedure and will include two rounds 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 GM soybean line, DAS-68416-4, has been developed that is tolerant to the herbicides 2,4-dichlorophenoxyacetic acid (2,4-D) and glufosinate ammonium. Tolerance to 2,4-D is achieved through the introduction of the *aad-12* gene, from *Delftia acidovorans*, expressing the protein aryloxyalkanoate dioxygenase (AAD-12). FSANZ has not previously assessed this specific protein but has assessed a closely related protein, AAD-1, in Application A1042. Tolerance to glufosinate ammonium is conferred by expression of the *pat* gene from *Streptomyces viridochromogenes*. The PAT protein has been assessed by FSANZ in a number of species including soybean.

FSANZ has completed a comprehensive safety assessment of food derived from soybean line DAS-68416-4 see **Supporting Document 1¹**). 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 DAS-68416-4 compared with that of conventional soybean cultivars. No public health and safety concerns were identified in this assessment.

On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from soybean line DAS-68416-4 is considered as safe and wholesome as food derived from other commercial corn cultivars.

Other assessment considerations

In assessing the Application, FSANZ has, in addition to considering the safety of food derived from soybean line DAS-68416-4, had regard to the following matters as prescribed in s 29 of the FSANZ Act:

- 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 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 DAS-68416-4, if approved, would be required to be labelled as genetically modified if it contains novel DNA or novel protein.

¹ SD1 - Safety Assessment for Application A1046
(<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1046food4807.cfm>)

Preferred Approach

Proceed to development of a food regulatory measure, to vary Standard 1.5.2 – Food produced using Gene Technology, to include food derived from herbicide-tolerant soybean line DAS-68416-4 in the Schedule.

Reasons for Preferred Approach

On the basis of the available evidence, proceeding to the development of a variation to the Code to give approval to the sale and use of food derived from herbicide-tolerant soybean line DAS-68416-4 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 DAS-68416-4.
- Food derived from soybean line DAS-68416-4 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 DAS-68416-4 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 DAS-68416-4. 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 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 soybean line DAS-68416-4.

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 2nd 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 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) 28 March 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 5636**

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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/applicationa1046food4807.cfm>

SD1: Safety Assessment Report: Application A1046 – Food Derived from Herbicide-Tolerant Soybean Line DAS-68416-4

INTRODUCTION

On 5 May 2010, Dow AgroSciences Australia Limited (Dow) submitted an Application seeking approval for food derived from soybean line DAS-68416-4 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

Soybean line DAS-68416-4 has been genetically modified (GM) to be tolerant to the herbicides 2,4-dichlorophenoxyacetic acid (2,4-D) and glufosinate ammonium. The purpose of the genetic modification is to provide soybean growers with a broader weed management option. Tolerance to 2,4-D has been conferred by the expression of the *aad-12* gene from *Delftia acidovorans* encoding an aryloxyalkanoate dioxygenase protein, AAD-12. FSANZ has not previously assessed this specific protein but has assessed a closely related protein, AAD-1, in Application A1042. Tolerance to glufosinate ammonium is conferred by expression of the *pat* gene from *Streptomyces viridochromogenes*. The PAT protein has been assessed by FSANZ in a number of species including soybean.

This Assessment includes a full scientific evaluation of food derived from soybean line DAS-68416-4 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 DAS-68416-4. Pre-market approval is necessary before food derived from this line may enter the Australian and New Zealand food supply. A variation to the Code, listing food derived from soybean line DAS-68416-4, must be approved by the FSANZ Board, and subsequently be 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 DAS-68416-4 is intended for cultivation in major soybean-producing countries (currently USA, Canada, Argentina and Brazil). Before its release into commercial markets, the Applicant is seeking regulatory approval for soybean line DAS-68416-4 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 DAS-68416-4. The Application is being assessed as a Major Procedure.

2. Current Standard

2.1 Background

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

2.2 Overseas approvals

Applications concerning soybean line DAS-68416-4 have been made to the appropriate agencies for food, feed and/or environmental approvals in the United States, Canada, South Korea, Taiwan, Argentina and the European Union. It is likely that dossiers will be submitted to the regulatory authorities of trade partners for import clearance including in Brazil, Japan, Mexico, Philippines, Colombia and South Africa.

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 for 1st Assessment

In completing the 1st 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 DAS-68416-4 comparable to food derived from conventional cultivars 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 soybean line DAS-68416-4 has been evaluated according to the safety assessment guidelines prepared by FSANZ(2007) 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

The safety assessment of soybean line DAS-68416-4 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 DAS-68416-4 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 line DAS-68416-4 contains two novel gene cassettes, one containing the *pat* gene and the other containing the *aad-12* gene. There are no antibiotic resistance marker genes present. Comprehensive molecular analyses indicate that there is a single insertion site containing one complete copy of each of the two cassettes. The introduced genetic elements are stably inherited from one generation to the next.

Expression analyses of the AAD-12 and PAT proteins showed that, in the plant parts tested, the AAD-12 is lowest in the roots and grain (approximately 16 µg/g dry weight) and highest in leaves (approximately 55 µg/g dry weight). PAT protein concentrations are much lower than those for AAD-12 but similarly, the leaves contain the highest levels (approximately 11 µg/g dry weight) and the roots contain the lowest levels (approximately 2 µg/g dry weight). Both proteins conform in size and amino acid sequence to that expected, and do not exhibit any post-translational modification including glycosylation.

In relation to potential toxicity and allergenicity, the Applicant did not supply data for the PAT protein but it is notable that a history of exposure to the PAT protein has shown it is inherently non-toxic to mammals and does not exhibit any potential to be allergenic to humans. For the AAD-12 protein, bioinformatic studies confirmed the lack of any significant amino acid sequence similarity to known protein toxins or allergens; a digestibility study demonstrated that the protein would be rapidly degraded in the stomach following ingestion; and a thermolability study showed that the protein is inactivated by heating. An acute oral toxicity study in mice also confirmed the absence of toxicity of AAD-12 in animals. Taken together, the evidence indicates that AAD-12 is unlikely to be toxic or allergenic to humans.

With regard to herbicide metabolites, use of PAT to confer tolerance to glufosinate ammonium has been previously considered in a wide range of food crops, including soybean, and therefore glufosinate ammonium residues were not considered in the Safety Assessment. The major residue generated on soybean line DAS-68416-4 as a result of spraying with 2,4-D is dichlorophenol. This residue is the same as that found on conventional crops sprayed with 2,4-D and would be present at very minor levels; there are no safety concerns.

Detailed compositional analyses were done to establish the nutritional adequacy of seed-derived products from soybean line DAS-68416-4 under four herbicide-spraying regimes.

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 DAS-68416-4 when compared with the non-GM control or with the range of levels found in commercial soybean cultivars.

Conclusion

No potential public health and safety concerns have been identified in the assessment of soybean line DAS-68416-4. On the basis of the data provided in the present Application, and other available information, food derived from soybean line DAS-68416-4 is considered to be 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 DAS-68416-4, if approved, would be required to be labelled as genetically modified if it contains novel DNA or novel protein.

6.2 Detection Methodology

As part of the Application, the Applicant is required to confirm that there is detection methodology for the GM food. For soybean line DAS-68416-4, there is methodology involving the use of the polymerase chain reaction for DNA detection. Additionally, the Applicant has developed immunoassay technology for detection of the AAD-12 protein. A description of this technology has been supplied to FSANZ but is Confidential Commercial Information. Because of the technology involved, these detection methods are likely to be restricted to specialist laboratories.

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 provisions. 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 are no non-regulatory options for this Application. Two regulatory options identified in relation to the proposed variations to Standard 1.5.2 are:

Option 1 – Reject application

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

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

Proceed to development of a food regulatory measure to vary Standard 1.5.2 to permit the sale and use of food derived from soybean line DAS-68416-4.

7.1 Affected Parties

The affected parties may include the following:

- Consumers of corn-containing food products, particularly those concerned about the use of biotechnology to generate new crop varieties.
- Industry sectors:
 - food importers and distributors of wholesale ingredients
 - processors and manufacturers of corn-containing food products
 - food retailers
- Government:
 - enforcement agencies
 - national Governments, in terms of trade and World Trade Organization (WTO) obligations.

It is the Applicant's hope that soybean line DAS-68416-4 be commercially cultivated primarily in major soybean-growing countries. There is no intention to apply for approval to cultivate this variety in either Australia or New Zealand. The cultivation of any GM crop 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 Risk Management Authority (ERMA) 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 DAS-68416-4.

No impact on consumers wishing to avoid GM foods, as food from soybean line DAS-68416-4 is not currently permitted in the food supply.

Potential increase in price of imported soybean foods due to requirement for segregation of soybean line DAS-68416-4.

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 DAS-68416-4 were to be commercialised overseas.

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

8.2.2 Option 2 –Proceed to development of a food regulatory measure

Consumers: Broader availability of imported soybean products as there would be no restriction on imported foods containing soybean line DAS-68416-4.

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

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

Government: Benefit that if soybean line DAS-68416-4 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 DAS-68416-4 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 DAS-68416-4 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 DAS-68416-4 would be required to be labelled.

7.3 Comparison of Options

As food from soybean line DAS-68416-4 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 DAS-68416-4 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 DAS-68416-4 from those containing approved soybean lines which would be likely to increase the costs of imported soybean-derived 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 food derived from herbicide-tolerant soybean line DAS-68416-4 is therefore the preferred option.

COMMUNICATION AND CONSULTATION STRATEGY

8. Communication

The communication strategy applied to this Application involves emailing/ mailing alerts to subscribers and interested parties, and placing the reports on the FSANZ website. In addition, FSANZ may issue a media release drawing journalists' attention to this Application.

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

Public comments on this 1st Assessment will be used in preparing the 2nd Assessment, which will 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 soybean line DAS-68416-4 is not subject to review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the relevant changes to the Code in the national press and on the website.

9. 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 herbicide-tolerant soybean line DAS-68416-4.

As this Application is being assessed as a Major Procedure, there will be two rounds of public comment.

9.1 World Trade Organization

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 inclusion of food derived from soybean line DAS-68416-4 in the Code would have a trade enabling effect as it would permit any foods containing this line of soybean 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

10. Conclusion and Preferred Approach

Preferred Approach

Proceed to development of a food regulatory measure to vary Standard 1.5.2 - Food produced using Gene Technology, to include food derived from herbicide-tolerant soybean line DAS-68416-4 in the Schedule.

10.1 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 DAS-68416-4 in Australia and New Zealand is proposed on the basis of the available 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 DAS-68416-4.
- Food derived from soybean line DAS-68416-4 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 DAS-68416-4 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 DAS-68416-4. 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.

11. Implementation and Review

Following the consultation period for this document, a 2nd 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.

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%202 .pdf](http://www.foodstandards.gov.au/srcfiles/GM%20FINAL%20Sept%2007L%202.pdf).