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

6 July 2011
[13-11]

APPLICATION A1046
FOOD DERIVED FROM HERBICIDE-TOLERANT SOYBEAN LINE DAS-68416-4
2nd 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 DAS-68416-4 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 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, which includes two rounds of public consultation. FSANZ has considered all submissions received in the 1st Assessment consultation period and has addressed issues, particularly those relevant to the safety of food derived from soybean line DAS-68416-4. Where necessary, additional/amended information has been incorporated into this 2nd Assessment Report.

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 enzyme 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 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 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 soybean 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.

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 DAS-68416-4 in the Schedule.

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) preparation of a draft variation to permit food derived from soybean line DAS-68416-4 in Standard 1.5.2. Following analysis of the potential costs and benefits of each Option on affected parties (consumers, the food industry and government), Option 2, preparation of a draft variation, 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

Consultation on the 1st Assessment was conducted over a period of six weeks. Six submissions were received. Summaries of these are in Attachment 2 of this Report. FSANZ has taken all submitters' comments into consideration in completing the 2nd Assessment Report. Specific issues relating to the safety of food derived from soybean line DAS-68416-4 have been addressed. Public comment is now invited on this Report, which includes a draft variation to Standard 1.5.2. Comments received in the second consultation period will be used to assist in preparing the Approval Report, to complete the assessment of the Application.

Invitation for Submissions

FSANZ invites public comment on this Report 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) 3 August 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

CONTENTS

SUPPORTING DOCUMENT

The following material, which was used in the preparation of this 2nd Assessment Report, is available on the FSANZ website at
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1046food4807.cfm

SD1: Safety Assessment Report (2nd Assessment): 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 enzyme, 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 enzyme has been assessed by FSANZ in a number of crop species including soybean.

The 1st Assessment Report included 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. Following a six week period of public consultation, the issues raised in submissions have been considered and addressed in this 2nd Assessment. Minor amendments to the Safety Assessment (**Supporting Document 1**) have also been made to address points of clarification. Public comment is now sought on this 2nd Assessment Report, which includes the draft variation to Standard 1.5.2, prior to preparation of the Approval Report and completion of the Application. All submissions relating to the 1st Assessment have been summarised in **Attachment 2** of this Report.

1. The Issue / Problem

The Applicant has developed 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 of America, 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.

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.

4. Risk Assessment Summary

4.1 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 from previous FSANZ assessments it has been concluded 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 (DCP). 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

5. Issues

5.1 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.

5.2 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 (refer to Section 8.1.2.1). Because of the technology involved, these detection methods are likely to be restricted to specialist laboratories.

6. 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 – 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 DAS-68416-4.

6.1 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 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.

6.2 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.

6.2.1 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.

6.2.2 Option 2 – Prepare a draft variation to Standard 1.5.2

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 soybean 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.

6.3 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

7. 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 2nd Assessment will be considered by the FSANZ Board in making its final decision.

The Applicant and individuals and organisations who make submissions on this Application will be notified at each stage of the assessment. If the FSANZ Board approves the draft variation to the Code, 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 by the Ministerial Council, 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.

8. Consultation

8.1 Public Consultation

Public submissions were invited on the 1st Assessment Report between 14 February and 28 March 2011. Comments were 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. Six submissions were received. A summary of these is provided in **Attachment 2** to this Report. Responses to the main issues raised regarding any risks to human safety if soybean line DAS-68416-4 was to be approved for food use, are provided below. Where necessary, FSANZ has addressed the issue through amendment to the Safety Assessment Report for soybean line DAS-68416-4.

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

8.1.1 General issues

During public consultation on the 1st Assessment Report for soybean line DAS-68416-4, the following general issues were raised concerning GM foods and their assessment:

- labelling of GM food
- lack of independent data on the safety of GM food

These two issues have been addressed by FSANZ in previous applications and, in addition, specific information is available on the FSANZ website (Table 1). It should be noted that the recommendations of the recent Review of Food Labelling Law and Policy were released at the end of January 2011, including recommendations for labelling of GM food. The Review essentially suggested that no changes be made to the current requirement to label GM food as 'genetically modified' if it contains novel DNA or protein, or has altered characteristics. The Review does provide recommendations to rescind the current exemptions for flavours and food service outlets and provides other recommendations regarding enforcement and monitoring. However, since these recommendations are not directly relevant to this Application, the outcomes of the Labelling Review are unlikely to impact on this assessment. An official response to the Review will be considered by the Australia New Zealand Food Regulation Ministerial Council in December 2011.

Table 1: Information regarding GM food on the FSANZ website

Issue	Web link
Labelling	http://www.foodstandards.gov.au/_srcfiles/GM%20Foods_text_pp_final.pdf http://www.foodstandards.gov.au/consumerinformation/gmfoods/frequentlyaskedquestionsongeneticallymodifiedfoods/part3labellingofgmfo4659.cfm
Lack of independent data to inform the risk assessment	http://www.foodstandards.gov.au/consumerinformation/gmfoods/ http://www.foodstandards.gov.au/consumerinformation/gmfoods/frequentlyaskedquestionsongeneticallymodifiedfoods/part2safetyassessmen4658.cfm

8.1.2 Specific issues

A number of issues specific to the assessment of soybean line DAS-68416-4 were raised in submissions and are addressed in the following responses.

8.1.2.1 Confidentiality of the detection methodology

The NSW Food Authority expressed concern that detection methodology used for compliance purposes has been given Confidential Commercial Information (CCI) status by FSANZ.

The applicant sought and was granted CCI on the DNA sequence of the insert and flanking border regions, the primer sequences used for cloning of the insert and confirmation of the event, and an ELISA method for protein determination. Sequence information is commonly given CCI status since the information is of commercial value to the Applicant and may provide information that would gratuitously benefit competitors. This granting of CCI does not preclude the Applicant from supplying compliance-testing laboratories with the information needed for event-specific testing purposes and, in reality, once a GM food has been approved and is ready for commercialization, the PCR method and sequence information is released to such laboratories.

In the case of the protein detection method, CCI was granted because the methodology is the subject of a patent application. Disclosure of the method would jeopardize the patent application. Once the patent has been filed, the information would no longer be CCI and would be publicly available.

8.1.2.2 Metabolism of 2,4-D in non-GM plants

The NZ Ministry of Agriculture and Forestry sought clarification of the metabolism of 2,4-D in plants not containing the AAD-12 enzyme.

This has been addressed in an amended Section 4 of the Safety Assessment (SD1). It should be noted that the Safety Assessment does not state that the 'amount' of dichlorophenol (DCP) residue would be the same as that found in conventional crops; what is stated is that the same residue is found in DAS-68416-4 and conventional crops.

8.1.2.3 Benefit cost analysis

Queensland Health requested information on advice supplied to the Office of Best Practice Regulation and on information used in the benefit cost analysis,

These two points are addressed in Section 7 of the 1st Assessment Report and Section 6 of the 2nd Assessment Report.

8.2 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.

There are not any relevant international standards and varying the Code to allow food derived from soybean line DA-68416-4 is unlikely to have a significant adverse effect on international trade 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.

Therefore, notification to the WTO under Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements is not considered necessary.

CONCLUSION

9. 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 herbicide-tolerant soybean line DAS-68416-4 in the Schedule.

9.1 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) preparation of a draft variation to permit food derived from soybean line DAS-68416-4 in Standard 1.5.2. Following analysis of the potential costs and benefits of each Option on affected parties (consumers, the food industry and government), Option 2, preparation of a draft variation, 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.

10. Implementation and Review

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%20_2_.pdf.

ATTACHMENTS

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

Attachment 1

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

Food Standards (Application A1046 – Food derived from Herbicide-tolerant Soybean Line DAS-68416-4) 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 A1046 – Food derived from Herbicide-tolerant Soybean Line DAS-68416-4) 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 DAS-68416-4	

Attachment 2

Summary of Public Submissions on 1st Assessment Report

Submitter	Comments
Department of Health, Victoria	• Supports approval of the Application.
NSW Food Authority	• Generally supportive of the approval. • Is concerned that the detection methodology is Confidential Commercial Information.
Ministry of Agriculture & Forestry (NZ)	• Agrees that no public health or safety concerns have been identified. • Suggests that data need to be included in the Safety Assessment to demonstrate the claim that the amount of DCP residue in DAS-68416-4 is the same as that found in conventional crops.
Australian Food & Grocery Council	• Supports approval on the basis that there is no identified risk to public health & safety. • Considers that Standard 1.5.2 ensures adequate information to consumers to make informed choices.
Queensland Health (whole of Queensland Government response)	• Neither supports nor opposes approval. • Requests an update on progress of applications concerning DAS-68416-4 made to other regulatory agencies around the world. • Expresses concern about the lack of independence of Study Reports. • Seeks advice about the benefit cost analysis and advice supplied to the Office of Best Practice Regulation. • Expresses a desire for Queensland Health Forensic and Scientific Services to be provided with methodology for compliance testing.
Complementary Healthcare Council of Australia	• Supports approval of the Application providing there are adequate labelling provisions • Requests process labelling • Notes that independent assessment by the OGTR would be required for environmental release of DAS-68416-4 in Australia