



22 March 2011
[6-11]

APPLICATION A1042 FOOD DERIVED FROM HERBICIDE-TOLERANT CORN LINE DAS-40278-9 2nd ASSESSMENT REPORT

EXECUTIVE SUMMARY

Main points are:

- **The Application seeks approval for food derived from a genetically modified (GM), herbicide-tolerant corn 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 corn line DAS-40278-9 in Standard 1.5.2.**
- **At present, there is no approval to grow this GM corn 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 corn 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 21 January 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) corn line DAS-40278-9, 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 corn line DAS-40278-9. 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 corn line, DAS-40278-9, has been developed that is tolerant to the herbicides 2,4-dichlorophenoxyacetic acid (2,4-D) and quizalofop-P-ethyl.

This tolerance is achieved through the introduction of the *aad-1* gene, from *Sphingobium herbicidovorans*, expressing the enzyme aryloxyalkanoate dioxygenase (AAD-1); FSANZ has not previously assessed this protein.

FSANZ has completed a comprehensive safety assessment of food derived from corn line DAS-40278-9 (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 corn line DAS-40278-9 compared with that of conventional corn 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 corn line DAS-40278-9 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 corn line DAS-40278-9, 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 *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 corn line DAS-40278-9, 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 corn line DAS-40278-9 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 corn line DAS-40278-9 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 corn line DAS-40278-9.
- Food from herbicide-tolerant corn line DAS-40278-9 is equivalent to that from other commercially available corn cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of food derived from herbicide-tolerant corn line DAS-40278-9 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 corn line DAS-40278-9. 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

Consultation on the 1st Assessment was conducted over a period of eight weeks. Nine 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 corn line DAS-40278-9 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 and the draft variation 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) 19 April 2010

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222**

**Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel (04) 978 5636**

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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/applicationa1042food4758.cfm>

SD1: Safety Assessment Report (2nd Assessment): Application A1042 – Food Derived from Herbicide-Tolerant Corn Line DAS-40278-9

INTRODUCTION

On 21 January 2010, Dow AgroSciences Australia Limited (Dow) submitted an Application seeking approval for food derived from corn line DAS-40278-9 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

Corn line DAS-40278-9 has been genetically modified (GM) to be tolerant to the herbicides 2,4-dichlorophenoxyacetic acid (2,4-D) and quizalofop-P-ethyl. The trait has been conferred by the expression of the *aad-1* gene from *Sphingobium herbicidovorans* encoding an aryloxyalkanoate dioxygenase protein, AAD-1. The purpose of the genetic modification is to provide corn growers with a broader weed management option.

The 1st Assessment Report included a full scientific evaluation of food derived from corn line DAS-40278-9 according to FSANZ guidelines (FSANZ, 2007) to assess its safety for human consumption. Following an eight 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 or typographical errors. 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 corn line DAS-40278-9. 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 corn line DAS-40278-9, 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.

Corn line DAS-40278-9 is intended for cultivation in North America. Before its release into commercial markets, the Applicant is seeking regulatory approval for corn line DAS-40278-9 in a number of trading markets, including Australia and New Zealand. This is necessary because once it is cultivated on a commercial-scale, processed corn products imported into Australia and New Zealand could contain components derived from corn line DAS-40278-9. 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 corn line DAS-40278-9 have been made to the appropriate agencies for food, feed and/or environmental approvals in the United States, Canada, Japan, South Korea, Taiwan, Mexico, 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, 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 corn line DAS-40278-9 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 corn line DAS-40278-9 included the following key elements: a characterisation of the transferred genes, their origin, function and stability in the corn genome; the changes at the level of DNA, protein and in the whole food; detailed compositional analyses; evaluation of intended and unintended changes; and the potential for the newly expressed proteins to be either allergenic or toxic in humans.

The assessment of corn line DAS-40278-9 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.

4.2 Outcomes of the Safety Assessment

Comprehensive molecular analyses of corn line DAS-40278-9 indicate there is one insertion site at a single genetic locus. This site contains one copy of the *aad-1* gene. Breeding over ten generations has confirmed stability of the introduced genetic elements and segregation data indicate their Mendelian inheritance. There are no antibiotic-resistance marker genes present in the line.

Aryloxyalkanoate dioxygenases are a class of enzymes found in common soil bacteria and hence there has been human exposure to the enzymes through normal dietary intake of fresh fruits and vegetables. The AAD-1 protein is expressed in leaves, pollen, roots, grain and forage of corn line DAS-40278-9, with the average content in mature grain being 4.8 µg/g dry weight (range 1.07-9.10 µg/g), considered to be a low level. The protein conforms in size and amino acid sequence to that expected, is immunoreactive to the corresponding antibody and is not glycosylated.

Bioinformatic studies with the AAD-1 protein confirmed the absence of any biologically significant amino acid sequence similarity to known protein toxins or allergens and digestibility studies demonstrated that the protein would be rapidly degraded following ingestion, similar to other dietary proteins. An acute oral toxicity study in mice with the AAD-1 protein confirmed the absence of toxicity. Taken together with the history of previous dietary exposure, the evidence indicates that the AAD-1 protein is neither toxic, nor likely to be allergenic, in humans.

The major residues generated on corn line DAS-40278-9 as a result of spraying with 2,4-D and quizalofop-P-ethyl are not novel. The residues are the same as those found on conventional crops sprayed with 2,4-D or quizalofop-P-ethyl. Residue data, derived from supervised trials, indicate that the residue levels for both herbicides are below the limit of quantitation. In the absence of any measurable exposure to either parent herbicide or their metabolites, the risk to public health and safety is likely to be negligible.

Detailed compositional analyses were done to establish the nutritional adequacy of grain-derived products from corn DAS-40278-9. The compositional data are consistent with the conclusion that there are no relevant significant differences in the levels of key components in grain from corn DAS-40278-9 when compared with conventional corn cultivars currently on the market.

Conclusion

No potential public health and safety concerns have been identified in the assessment of corn line DAS-40278-9. On the basis of the data provided in the present Application, and other available information, food derived from corn line DAS-40278-9 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

RISK MANAGEMENT

5. Issues

5.1 Labelling

In accordance with general labelling provisions, food derived from corn line DAS-40278-9, 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 corn line DAS-40278-9, 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-1 protein. A description of this technology has been supplied to FSANZ but is currently Confidential Commercial Information (refer to Section 8.1.2.2). 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 variation 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 corn line DAS-40278-9.

6.1 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 corn line DAS-40278-9 be commercially cultivated primarily in Northern America. 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 corn products to those products that do not contain corn line DAS-40278-9.

No impact on consumers wishing to avoid GM foods, as food from corn line DAS-40278-9 is not currently permitted in the food supply.

Potential increase in price of imported corn foods due to requirement for segregation of corn line DAS-40278-9.

Government: Potential impact if considered inconsistent with WTO obligations but impact would be in terms of trade policy rather than in government revenue.

Industry: Possible restriction on imports of corn food products if corn line DAS-40278-9 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 draft food regulatory measure

Consumers: Broader availability of imported corn products as there would be no restriction on imported foods containing corn line DAS-40278-9.

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

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

Government: Benefit that if corn line DAS-40278-9 was detected in corn imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of corn line DAS-40278-9 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 corn derivatives would benefit as foods derived from corn line DAS-40278-9 would be compliant with the Code, allowing broader market access and increased choice in raw materials.

Retailers may be able to offer a broader range of corn products or imported foods manufactured using corn derivatives.

Possible cost to food industry as some food ingredients derived from corn line DAS-40278-9 would be required to be labelled.

6.3 Comparison of Options

As food from corn line DAS-40278-9 has been found to be as safe as food from conventional cultivars of corn, Option 1 is likely to be inconsistent with Australia's and New Zealand's WTO obligations. Option 1 would also offer little benefit to consumers, as approval of corn line DAS-40278-9 by other countries could limit the availability of imported corn products in the Australian and New Zealand markets. In addition, Option 1 would result in the requirement for segregation of any products containing corn line DAS-40278-9 from those containing approved corn lines which would be likely to increase the costs of imported corn-derived 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 food derived from herbicide-tolerant corn line DAS-40278-9 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 used in preparing an Approval Report that will be considered 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, and 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 corn line DAS-40278-9 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 15 December 2010 and 9 February 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 corn line DAS-40278-9. Nine 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 corn line DAS-40278-9 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 corn line DAS-40278-9.

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 corn line DAS-40278-9, 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 and, with regard to GM labelling, essentially suggested that no changes be made.

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 corn line DAS-40278-9 were raised in submissions and are addressed in the following responses. Where necessary, amendments have been made to the Safety Assessment Report.

8.1.2.1 Adverse effect of the consumption of herbicides sprayed on the crop

The use of agricultural chemicals is strictly controlled in Australia and any food products sold, including imported foods, must not have chemical residues greater than the relevant maximum residue limit (MRL). The MRL is the maximum amount of residue expected to be found on a food when the agricultural chemical has been used responsibly. It is much lower than the safe limit for consumption by humans. In setting a maximum limit, the toxicity of the herbicide and any metabolites are comprehensively assessed irrespective of whether the crop concerned is GM or non-GM.

The setting of an MRL (if an MRL is necessary) requires a variation to Standard 1.4.2 of the Code and is a separate process from the safety considerations included in the Safety Assessment Report prepared in response to a request to vary Standard 1.5.2.

8.1.2.2 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.

8.1.2.3 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, in particular the cost of compliance testing.

These two points have now been addressed in Section 6 of this 2nd Assessment Report.

8.1.2.4 Metabolism of 2,4-D and quizalofop-P-ethyl in non-GM plants

The NZ Ministry of Agriculture and Forestry sought clarification of the metabolism of these two herbicides in plants not containing the AAD-1 enzyme.

This has been addressed in an amended Section 4 of the Safety Assessment (SD1)

8.1.2.5 Compositional analyses

The NZ Ministry of Agriculture and Forestry sought some further discussion of those analytes in which significant differences were found between the control and DAS-40278-9 plants.

This has been addressed in an amended Section 6 of the Safety Assessment (SD1)

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.

The inclusion of food derived from corn line DAS-40278-9 in the Code would have a trade enabling effect as it would permit any foods containing this line of corn to be imported into Australia and New Zealand and sold, where currently they would be prohibited.

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 corn line DAS-40278-9 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 corn line DAS-40278-9 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 corn line DAS-40278-9.
- Food from herbicide-tolerant corn line DAS-40278-9 is equivalent to that from other commercially available corn cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of food derived from herbicide-tolerant corn line DAS-40278-9 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 corn line DAS-40278-9. 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.

10. Implementation and Review

Following the consultation period for this 2nd Assessment Report, 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%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*

Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

Commencement: On gazettal

[1] **Standard 1.5.2** of the *Australia New Zealand Food Standards Code* is varied by inserting in numerical order in the Schedule –

	7.7	Food derived from herbicide-tolerant corn line DAS-40278-9	
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Attachment 2

Summary of Public Submissions on 1st Assessment Report

Submitter	Comments
Anna Clements (Private)	<ul style="list-style-type: none"> Neither supports nor opposes the approval. Considers that current GM labelling laws are inadequate and that consumers are unable to make an informed choice re GM foods.
Eric Smith (Private)	<ul style="list-style-type: none"> Neither supports nor opposes approval. Concerned with the adverse affects of consumption of the herbicide residues from the crop and urges FSANZ to consider the health impacts.
NSW Food Authority	<ul style="list-style-type: none"> Generally supportive of the approval. Is concerned that the detection methodology is Confidential Commercial Information. Points out a typographical error in Table 8 of the Safety Assessment.
Food Technology Association of Australia	<ul style="list-style-type: none"> Supports approval of the Application.
Ministry of Agriculture & Forestry (NZ)	<ul style="list-style-type: none"> Agrees that no public health or safety concerns have been identified. Seeks clarification of the metabolism of 2,4-D and quizalofop-P-ethyl in conventional crops not containing the AAD-1 enzyme. Seeks clarification of significant treatment effects in the compositional analysis.
Australian Food & Grocery Council	<ul style="list-style-type: none"> Supports approval on the basis that there is no identified risk to public health & safety. Supports the advice that labelling of foods derived from corn line DAS-40278-9 will be required if they contain novel DNA or novel protein.
Queensland Health (whole of Queensland Government response)	<ul style="list-style-type: none"> Neither supports nor opposes approval. Raises the point that Standard 1.4.2 may need to be amended with regard to quizalofop-P-ethyl. Requests an update on progress of applications concerning DAS-40278-9 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 concern about the cost of compliance testing.
Victorian Department of Health	<ul style="list-style-type: none"> Supports approval of the Application.
Paul Elwell-Sutton (Private)	<ul style="list-style-type: none"> Does not support approval. Expresses concern about the lack of independence of the studies provided.