



15 December 2010
[25-10]

APPLICATION A1042 FOOD DERIVED FROM HERBICIDE-TOLERANT CORN LINE DAS-40278-9 1st 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 proceeding to the development of a 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 and will include two rounds of public consultation.

Safety Assessment

A new genetically modified (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 protein 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 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 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.

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.

Impact of Regulatory Options

Following satisfactory completion of the safety assessment, 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.

Assessing the Application

In assessing the Application, FSANZ has had regard to the following matters as prescribed in s.29 of the *Food Standards Australia New Zealand Act 1991* (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.

¹ SD1 - Safety Assessment for Application A1042
(<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1042food4758.cfm>)

Preferred Approach

To proceed to the development of a food regulatory measure to vary Standard 1.5.2 – Food produced using Gene Technology, to include food derived from herbicide-tolerant corn line DAS-40278-9 in the Table to clause 2.

Reasons for Preferred Approach

On the basis of the available scientific 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 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 derived from corn line DAS-40278-9 is equivalent to that derived from the conventional counterpart and other commercially available corn cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of foods derived from corn line DAS-40278-9 will be required if they contain novel DNA or novel protein.
- A regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is Option 2, the development of a food regulatory measure.
- 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 corn line DAS-40278-9.

As this Application is being assessed under the 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.

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 section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the 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) 9 February 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 6036
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/applicationa1042food4758.cfm>

SD1: Safety Assessment Report: 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.

This Assessment includes 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. 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 corn line DAS-40278-9. Pre-market approval is necessary before food product derived from this line may enter the Australian and New Zealand food supply. A variation to the Code, 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 Table to clause 2 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.

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 corn line DAS-40278-9 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 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.

5. Risk Assessment Summary

5.1 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.

5.2 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 lines/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 likely to be 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. 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.

5.3 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

6. Issues raised

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.

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. 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. Options

There are no non-regulatory options for this Application. The two regulatory options available for this Application are:

7.1 Option 1 – Reject Application

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

7.2 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 corn line DAS-40278-9.

8. Impact Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

8.1 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.

8.2 Benefit Cost Analysis

8.2.1 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.

8.2.2 Option 2 – Proceed to development of a 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.

8.3 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 assessments, the potential benefits of Option 2 outweigh the potential costs. A variation to Standard 1.5.2 giving approval to herbicide-tolerant corn line DAS-40278-9 is therefore the preferred option.

Communication and Consultation Strategy

9. 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 corn line DAS-40278-9 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.

10. 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 corn line DAS-40278-9.

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

10.1 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 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.

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

11. Conclusion and Preferred Approach

Preferred Approach

To proceed to the development of a food regulatory measure to vary Standard 1.5.2 – Food produced using Gene Technology, to include food derived from herbicide-tolerant corn line DAS-40278-9 in the Table to clause 2.

11.1 Reasons for Preferred Approach

The development of a variation to the Code to give approval to the sale and use of food derived from herbicide-tolerant corn line DAS-40278-9 in Australia and New Zealand is proposed on the basis of the available scientific evidence, for the following reasons:

- The safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce herbicide-tolerant corn line DAS-40278-9.
- Seed from herbicide-tolerant corn line DAS-40278-9 is equivalent to other commercially available corn cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of certain foods derived from herbicide-tolerant corn line DAS-40278-9 will be required in the ingredients list if they contain novel DNA or novel protein.
- A regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is Option 2, a variation to the Code, and
- There are no other measures that would be more cost-effective than a variation to Standard 1.5.2 and could achieve the same end.

12. Implementation and Review

Following the consultation period for this document, 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%20_2_.pdf.