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

19 August 2011
[15-11]

APPLICATION A1042
FOOD DERIVED FROM HERBICIDE-TOLERANT CORN LINE DAS-40278-9
APPROVAL REPORT

EXECUTIVE SUMMARY

Main points are:

- **The Application seeks approval for food derived from a genetically modified (GM), insect-protected and herbicide-tolerant corn line.**
- **The Safety Assessment did not identify any potential public health and safety concerns.**
- **This Report recommends the approval 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 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 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 was assessed under the Major Procedure.

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.

Decision

To approve the 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 Decision

On the basis of the available evidence, the draft variation to the Code to allow the sale and use of food derived from herbicide-tolerant corn line DAS-40278-9 in Australia and New Zealand has been approved 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 draft variation to Standard 1.5.2; or (2) approval of the draft variation to permit the sale and use 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 the 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

As this Application was assessed as a Major Procedure, there were two rounds of public comment. Consultation on the 1st Assessment was conducted over a period of eight weeks; nine submissions were received. Consultation on the 2nd Assessment was conducted over a period of four weeks; 59 were received and a summary of these is provided at **Attachment 2.**

FSANZ has taken all submitters' comments into consideration in completing the assessment of this Application, and has addressed issues, particularly those relevant to the safety of food derived from corn line DAS-40278-9. Additional information was incorporated into the Safety Assessment where necessary. Responses to the 2nd Assessment Report were taken into account in the Board's decision.

CONTENTS

SUPPORTING DOCUMENTS

The following material, which was used in the preparation of this Approval Report, is available on the FSANZ website at
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1042food4758.cfm

SD1: Safety Assessment Report (Approval)

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.

FSANZ has completed a scientific evaluation of food derived from corn line DAS-40278-9 according to FSANZ guidelines (FSANZ 2007) to assess its safety for human consumption. The 1st Assessment Report prepared in relation this Application was released in December 2010 for an eight-week public consultation period. Issues raised in submissions were considered and addressed in the 2nd Assessment Report, which was released in March 2011 for a four week public consultation period. Comments received during this second consultation period have been considered in completion of this Approval Report. All submissions relating to the 2nd Assessment Report have been summarised in **Attachment 2**.

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 was 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 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 of America, Canada, Japan, South Korea, Taiwan, Mexico, Argentina and the European Union. Approval for food and feed use was given by the U.S. Food and Drug Administration on 14 April 2011.The remaining applications are still under consideration.

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 section 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 (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.

DAS-40278-9 is not a popcorn or sweet corn line. The grain would be mostly processed into refined products such as corn syrup and corn starch which, because of processing, contain negligible levels of any protein or DNA. Similarly, in the production process for refined corn oil, protein and DNA are likely to be reduced below the level of detection. Products such as meal (used in bread and polenta) and grits (used in cereals) are likely to contain detectable levels of protein and DNA.

5.2 Detection Methodology

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

For corn line DAS-40278-9, there is methodology involving the use of the polymerase chain reaction for DNA detection. The methodology has been submitted to the European Commission Joint Research Centre which publishes a GMO Detection Methods database (http://gmo-crl.jrc.ec.europa.eu/gmomethods/). Publication of the method will occur after validation and ring trial.

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 8.1.2.6) as the outcome of a patent application is still pending. The method will be released publicly once either the patent is granted or approval for DAS-40278-9 is given.

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 were:

Option 1 – Reject the draft variation

Reject the draft variation, thus maintaining the *status quo*.

Option 2 – Approve the draft variation

Approve the draft variation 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 intention that corn line DAS-40278-9 be commercially cultivated primarily in North America. There does not appear to be any 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 the draft variation

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 – Approve the draft variation

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 was 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 arising from the round of consultation on the 2nd Assessment were taken into account in the Board's decision.

The Applicant and individuals and organisations who made submissions on this Application were notified at each stage of the assessment. The FSANZ Board decision to approve the variation to the Code has been 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

As this Application was assessed under the Major Procedure, there were two rounds of public consultation. During both rounds of consultation, comments were specifically sought on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from corn line DAS-40278-9.

Public submissions were invited on the 1st Assessment Report between 15 December 2010 and 19 February 2011. Nine submissions were received on the 1st Assessment Report and these were summarised in Attachment 2 to the 2nd Assessment Report. Issues raised in submissions were considered and addressed in the 2nd Assessment Report, which was released for public comment between 22 March and 19 April 2011. The 59 submissions received during this second consultation period have been considered. All submissions relating to the 2nd Assessment Report have been summarised in **Attachment 2** to this Report. FSANZ has taken the submitters' comments relevant to food safety into account.

8.1.1 General issues

Responses to general issues raised, such as the safety of GM food including long-term health effects, GM food labelling, the relevance of long term feeding studies, data used to inform the Safety Assessment, and the likelihood of horizontal gene transfer to bacteria in the human gut are available from the FSANZ website (see Table 1).

In relation to the Safety Assessment, it should be noted that the data submitted by an Applicant and the conduct of the studies are subject to strict requirements outlined in the *Application Handbook*[1].

[1] The Application Handbook is available at (http://www.foodstandards.gov.au/foodstandards/changingthecode/applicationshandbook.cfm).

In turn, these requirements are based on widely recognised principles for assessing the safety of whole foods.

The principles have been established since the 1990s at the international level by bodies such as the Codex Alimentarius Commission, the World Health Organization and the Organisation for Economic Cooperation and Development (OECD). Similar assessment procedures are followed in Canada, Japan, the European Union and the United States of America.

Another common issue raised in submission on GM applications in general, is that there are independent studies that have shown GM foods to be unsafe. The same set of studies is frequently cited by opponents of GM foods. A number of these studies have been evaluated by FSANZ (see http://www.foodstandards.gov.au/_srcfiles/FSANZ%20Table.pdf), as well as other food regulatory agencies and independent experts around the world, and the claims cannot be substantiated. Criticisms of the studies have been widely published by independent scientists who have discovered serious flaws in the study methods or in the interpretation of the results.

A common request by submitters to recent GM applications, including this Application, is that FSANZ not approve any more GM applications until the report from the latest Review of Labelling Law and Policy is written, and recommendations reviewed and implemented. FSANZ has a legal obligation to consider all applications seeking to amend the Code, within a statutory timeframe and this cannot be held up pending the outcome(s) of processes that may be in progress at the time an application is being assessed. If, after an approval has been made, information comes to light that alters the conclusions reached in an assessment then the approval can be revoked or the risk management strategies altered. It is worth noting that the recommendations of the recent Labelling Review were released at the end of January 2011.

With regard to GM labelling, the Labelling 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. A whole-of-government response to the Review is expected to be considered by the Ministerial Council in December 2011.

A number of submitters have raised issues associated with the environment, especially regarding the use of herbicides, or the actual growing of GM crops. Consideration of these issues is beyond the remit of FSANZ which is concerned primarily with the safety of food that is consumed. It is also salient to note that there is currently no intention of growing corn line DAS-40278-9 in Australia or New Zealand.

An on-going concern with submitters to a number of GM applications has been the perceived lack of availability of application dossiers and/or the cost involved in being able to obtain the dossiers. As of 1 May 2011, FSANZ will be placing the dossiers for all new applications on the FSANZ website and, over time, the plan is to gradually add all previous application dossiers. The dossier for A1042 has already been placed on the website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1042food4758.cfm.

The Sustainable Future Institute and GE Free New Zealand argue that FSANZ favours the "acceptance" of this Application based on political and economic international trade relationships, as opposed to proper assessment of public health.

As already stated (Executive Summary and Section 3), the primary objective of FSANZ in developing or varying a food regulatory measure (s 18 of the FSANZ Act), is the protection of public health and safety. Accordingly, the Safety Assessment forms the central component in considering an application. If the Safety Assessment identifies a safety concern it is unlikely that the food would be considered for approval.

If, on the other hand, the Safety Assessment does not identify any safety concerns, then a number of other statutory obligations, including Australia's and New Zealand's ability to meet their obligations under the WTO, must be considered in relation to the approval.

One private submitter stated that FSANZ has approved GM foods as safe which other countries are declaring unsafe e.g. NK603, MON810, MON863 corn lines. The following countries have approved food derived from at least one of these lines: Argentina, Brazil, Canada, European Union, Japan, Korea, Philippines, South Africa, Taiwan and the United States of America. Five countries – Canada, Japan, Korea, Taiwan and the USA – have approved food from all three lines.

Table 1: Sources of Information, available on the FSANZ website, regarding GM Food

Issue	Specific web link
Safety of GM food	Safety Assessment of Genetically Modified Foods http://www.foodstandards.gov.au/_srcfiles/GM%20Foods_text_pp_final.pdf
	Frequently Asked Questions on GM foods http://www.foodstandards.gov.au/foodmatters/gmfoods/frequentlyaskedquest3862.cfm
Labelling of GM food	Appendix 3: Safety Assessment of Genetically Modified Foods http://www.foodstandards.gov.au/_srcfiles/GM%20Foods_text_pp_final.pdf
	Frequently Asked Questions on GM foods Part III. Labelling of GM Foods http://www.foodstandards.gov.au/foodmatters/gmfoods/frequentlyaskedquest3862.cfm
	GM Labelling Review Report http://www.foodstandards.gov.au/newsroom/publications/gmlabellingreviewrep2460.cfm
Long term feeding studies	Section 7.6: Safety Assessment of Genetically Modified Foods http://www.foodstandards.gov.au/_srcfiles/GM%20Foods_text_pp_final.pdf
	Role of animal feeding studies in the safety assessment of genetically modified foods http://www.foodstandards.gov.au/consumerinformation/gmfoods/roleofanimalfeedings3717.cfm
Data used to inform the Safety Assess.	Food Matters GM Foods http://www.foodstandards.gov.au/foodmatters/gmfoods/
Horizontal gene transfer	Safety Assessment of Genetically Modified Foods Guidance Document http://www.foodstandards.gov.au/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf Section 7.4: Safety Assessment of Genetically Modified Foods http://www.foodstandards.gov.au/_srcfiles/GM%20Foods_text_pp_final.pdf

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 The herbicides that are to be sprayed on corn line DAS-40278-9

The major concerns raised by submitters were in relation to 2,4-D, such as the safety of its residues[2] particularly dioxins, its effects on human health, possible interactions with quizalofop-P-ethyl, and the levels that might be sprayed on the crop. One private submitter also questioned why FSANZ had not considered a 'safer option'.

It is not the role of FSANZ to evaluate whether a particular genetic modification is necessary or whether there are alternative options to the one proposed by the Applicant. FSANZ has a statutory obligation to consider, on a case-by-case basis, all applications seeking to amend the Code, and to focus on whether or not there are any safety issues with regard to consumption of the proposed food.

FSANZ does not have responsibility for assessing the environmental impacts or safe use of a herbicide other than in the context of a consideration of any food products that may be derived from a crop sprayed with a herbicide. Therefore, issues such as the predicted agricultural usage of herbicides and associated environmental implications, possible development of resistance, and occupational health and safety considerations of those who manufacture/apply the herbicides are beyond the legal scope of FSANZ.

For any GM application involving herbicide tolerance, it is likely that FSANZ will need to consider two separate aspects that relate to two separate Standards in the Code.

- In relation to Standard 1.5.2, it is paramount to consider whether novel metabolites are produced following the application of a herbicide and, if so, whether these are present in the final food and whether there are any toxicological concerns. This information is included in the Safety Assessment and considers whether appropriate health-based guidance values (i.e. Acceptable Daily Intake [ADI] or Acute reference Dose [ARfD] need to be established.

- A separate consideration involves Standard 1.4.2 – Maximum Residue Limits. In the case of food entering Australia via imports (i.e. the crop will not be grown in Australia), it may be necessary for FSANZ to amend the Maximum Residue Limit (MRL)[3]. Standard 1.4.2 does not however apply to New Zealand. Instead, the setting of MRLs for imported foods in that country is considered by the Ministry for Agriculture and Forestry (for inclusion in Maximum Residue Limits of Agricultural Compounds – see http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm).

Any food products (whether derived from GM or non-GM sources) sold in both Australia and New Zealand must not have chemical residues greater than the relevant MRL. The MRL for a herbicide is derived from data collected from field trials conducted under Good Agricultural Practice and is a legally enforceable limit. The results from field trials are used to establish an MRL only if the estimated intake of residue(s) does not exceed the ADI or ARfD, i.e. in undertaking a risk-based assessment to support inclusion of an MRL, the key issue is whether, in the context of the Australian/New Zealand diet, the consumption of chemical residues in the food remains below the health-based guidance values.

[2] A pesticide residue is any specified substance in food, agricultural commodities or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities that are considered to be of toxicological significance.

[3] For GM crops grown in Australia, establishment of an MRL is done through collaboration with the Australian Pesticides and Veterinary Medicines Authority (APVMA)

For GM applications, the process of amending MRLs is quite separate from the safety considerations included in the Safety Assessment and, at the time of preparation of this Approval Report still needs to be undertaken with regard to corn line DAS-40278-9. Variations to both Standard 1.5.2 and Standard 1.4.2/Maximum Residue Limits of Agricultural Compounds, if appropriate, would need to be gazetted before food derived from corn line DAS-40278-9 could legally be sold in Australia or New Zealand.

With regard to issues raised in submissions about the safety of the herbicides in a food context the following points are made:

- 2,4-D is already widely and safely used on food crops (JMPR 1974) and 2,4-D MRLs for a variety of plant-derived food commodities have currently been adopted by Codex (http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp).

- The Applicant has supplied data to show that no herbicide metabolites are produced in DAS-40278-9 that are not also produced in conventional crops sprayed with the herbicides.

- Contrary to claims made by GE-Free New Zealand, the Applicant has supplied the requisite residue studies. The results from field trials in which corn line DAS-40278-9 was sprayed with 2,4-D and quizalofop-P-ethyl at levels equivalent to the maximum seasonal rate showed that, on average, neither the parent compound nor residues could be detected in the grain.

- Notwithstanding the above, the U.S. Environmental Protection Agency (EPA) recently concluded (EPA 2005) that, with regard to dietary risk from 2,4-D sprayed on crops, “acute and chronic dietary exposures for food and drinking water do not exceed the Agency’s level of concern; therefore, no mitigation is warranted at this time for any dietary exposure to 2,4-D”.

- Dioxins are a family of around 200 chemicals which vary widely in toxicity with 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) being considered the most toxic. While food is one source of dioxins, other common sources include the burning of municipal and industrial waste and tobacco smoke. As dioxins tend to be stored in fat, the main dietary sources are meat, milk products and fish rather than fruit, vegetables and grains. While dioxins, including TCDD, were present as manufacturing contaminants in 2,4-D, since the 1990s there has been regulation to decrease the chance that TCDD is formed during the manufacturing process (EPA, 2005).

- The compositional analysis of line DAS-40278-9 compared an unsprayed non-GM control with each of four spray treatments involving DAS-40278-9 (see Section 6 of the Safety Assessment). The results indicated that the composition of line DAS-40278-9 whether sprayed or unsprayed was statistically indistinguishable from that of the non-GM control.

8.1.2.2 The AAD-1 protein

A number of submitters express concern about the safety, particularly toxicity, of the AAD-1 protein.

- GE Free New Zealand is concerned that the AAD-1 protein obtained from a bacterial system and used in several of the safety studies was produced in *Pseudomonas* not in *Sphingobium* (the source of the gene used for genetic modification) and hence the *Pseudomonas*-derived protein may not be a suitable surrogate.

- Additionally, GE Free NZ is concerned that the AAD-1 protein could have effects on the liver or could alter metabolic pathways. Concern was expressed about the inability to be able to conclude from the digestibility study that the AAD-1 protein was not destroyed in 16 minutes because of its binding to the SGF protein.

- MADGE, GE Free New Zealand, and two private submitters believe that adverse effects (multifocal erosions/ulcers in stomach glandular mucosa of a male mouse; dark focus in cerebrum of female mouse) were seen in two animals in the acute toxicity study and suggest that follow-up studies should have been done.

GE Free New Zealand was also critical of the manner in which the acute toxicity study was undertaken.

- GeneEthics cites a recent paper (Aris and Leblanc, 2011[4]) and a report (Heinemann, 2009[5]) as evidence that the AAD-1 protein may be harmful.

The AAD-1 protein used in the digestibility and acute toxicity studies was obtained from an *in vitro* GM bacterial (*Pseudomonas*) system since it was not possible to obtain sufficient protein from DAS-40278-9. This is a standard procedure and the bacterial species used to synthesise the protein is not important. What is important is that sufficient testing is done to ensure the bacterially-produced protein is structurally and functionally equivalent to the protein expressed in the plant. The Applicant supplied extensive comparative data to confirm this.

The results from the requisite studies on the AAD-1 protein did not raise any toxicity concerns. In relation to the specific issues raised, the following points can be made:

- In the SDS gels used in the digestibility study, the AAD-1 protein did not 'bind to the SGF protein'. On an SDS gel, faint bands from the SGF co-migrated with the AAD-1 band but the latter was sharp and clearly visible at time zero and had completely disappeared by 30 s. Similarly, in the Western blot, where no SGF bands were visible, the AAD-1 protein band disappeared completely after 30 s. This unambiguously demonstrates that AAD-1 is rapidly destroyed in gastric juices.

- The Applicant supplied an acute oral toxicity study for the AAD-1 protein even though the results from the requisite studies (Codex 2003) did not warrant the generation of additional toxicity data. Since an acute toxicity study was supplied, FSANZ evaluated the results. The study was performed according to OECD Guidelines. There were no deaths or clinical signs and all animals had gained weight by study termination. The gross pathology observations that were identified in two mice in the AAD-1 acute oral toxicity study were not accompanied by any degenerative changes to the organs in question or other visible signs that could trigger a concern.

  It is important to appreciate that the interpretation of any toxicological study needs to be biologically plausible. The *in vitro* studies have convincingly shown that the AAD-1 protein is enzymatically transformed to very short-chain peptides and/or amino acids under simulated gastric digestion conditions. In this context it is biologically implausible that degraded AAD-1 protein could be absorbed from the GI tract and cross blood-brain barrier to cause pathological lesions in the mouse brain (cerebrum).

[4] Aris A, Leblanc S (2011) Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada. Reproductive Toxicology, in press.
[5] Heinemann JA (2009) Report on animals exposed to GM ingredients in animal feed. Report prepared for the Commerce Commission of New Zealand.

Spontaneous stomach ulceration is reasonably common in *ad libitum* fed mice with an incidence in the range of 5-9% (Rehm et al. 1987). On this basis it is not possible to exclude an isolated occurrence as being part of the normal background incidence.

- The Aris and Leblanc (2011) paper cited by GeneEthics deals with pesticides associated with GM crops, specifically the herbicides glyphosate and glufosinate ammonium and the insecticidal protein Cry1Ab. This is of doubtful relevance to an evaluation of the safety of the AAD-1 protein since firstly the paper did not establish the source of the chemicals in question (an important point to establish since all the chemicals in question are also associated with non-GM sources), and secondly, the authors did not report or allege any adverse effects from the presence of the chemicals in the human subjects. FSANZ has prepared a Fact Sheet on the paper, available at http://www.foodstandards.gov.au/consumerinformation/gmfoods/fsanzresponsetostudy5185.cfm.

  The Heinemann (2009) report cited by GeneEthics, deals with the question of whether GM material (i.e. DNA or protein) that may be present in an animal feed could be detected in an animal that has eaten the feed. The author also discusses whether there is evidence of physiological or immunological responses in the animals as a result of eating the feed and concludes, from the results of a number of studies, that exposure to GM material could cause residual differences in the animals. There is no claim that these residual differences, if indeed they are real, are harmful.

8.1.2.3 Nutritional assessment

GE Free New Zealand is concerned that no nutritional impact studies were conducted.

The compositional analysis showed that there were no biologically significant nutritional changes in corn line DAS-40278-9 (either sprayed or not sprayed with herbicides) when compared to a non-GM control. In addition, the digestibility study indicated that AAD-1 is inactivated by digestive fluids and therefore there would be no potential dietary exposure to the functionally active protein. Given these considerations, there is no requirement for a dietary exposure assessment to be undertaken.

8.1.2.4 Compliance testing

Queensland Health expresses concern that detection methodology used for compliance purposes has been given Confidential Commercial Information (CCI) status by FSANZ.

This issue has been addressed in Section 5.2 of this Approval Report. 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.

8.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

Varying the Code to allow food derived from corn line DAS-40278-9 would have a trade enabling effect as it would permit the food to be imported into Australia and New Zealand and sold, where currently it is 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 was not considered necessary.

CONCLUSION

9. Conclusion and Decision

Decision

To approve the 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 Decision

On the basis of the available evidence, the draft variation to the Code to allow the sale and use of food derived from herbicide-tolerant corn line DAS-40278-9 in Australia and New Zealand has been approved 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 draft variation to Standard 1.5.2; or (2) approval of the draft variation to permit the sale and use 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 the 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 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

Codex (2003) Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. CAC/GL 45-2003. Codex Alimentarius. http://www.codexalimentarius.net/web/standard_list.do?lang=en

EPA (2005) Reregistration eligibility decision for 2,4-D. EPA 738-R-05-002. United States Environmental Protection Agency,

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_.pdfJMPR (1974) 290. 2,4-D. WHO Pesticide Residue Series 4, Joint FAO/WHO Meeting on Pesticide Residues.

http://www.inchem.org/documents/jmpr/jmpmono/v074pr13.htm

OECD (2001) Test No. 420: Acute Oral Toxicity - Fixed Dose Procedure. Organisation for Economic Co-operation and Development,

Rehm S, Sommer R, Deerberg F (1987) Spontaneous nonneoplastic gastric lesions in female Han:NMRI mice, and influence of food restriction throughout life. Veterinary Pathology 24(3):216–225

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 A1042 – Food derived from Herbicide-tolerant Corn Line DAS-40278-9) 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 A1042 – Food derived from Herbicide-tolerant Corn Line DAS-40278-9) 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 –

	2.x	Food derived from herbicide-tolerant corn line DAS-40278-9	

Attachment 2

Summary of issues raised in 2nd Assessment public submissions

Submitter	Comments
Ministry of Agriculture and Forestry (NZ)	• Neither supports nor opposes approval. • Accepts changes made to Section 4 of the Safety Assessment as a result of MAF comments made on the 1st Assessment Report. • Requests further wording changes to clarify the explanation of the statistical analyses in Section 6 of the Safety Assessment.
Queensland Health (Whole of QLD Govt response)	• Neither supports nor opposes approval. • Requests an update on progress of applications concerning DAS-40278-9 made to other regulatory agencies around the world. • Seeks advice about the benefit cost analysis and advice supplied to the Office of Best Practice Regulation[6]. • Expresses concern about compliance testing and the need for testing methodology to be made available to enforcement agencies.
Complementary Healthcare Council (Aus)	• Generally supports approval of the Application • Would like to see labelling of all products derived from DAS-40278-9 irrespective of whether or not novel DNA or novel protein is present. • Notes that there has been no request to grow line DAS-40278-9 in Australia or New Zealand.
GeneEthics (Aus)	• Opposes approval of this and all other GM applications on the grounds that evidence of the digestibility and degradation of protein and DNA in GM food has not been adequately considered. • Cites a recent paper (Aris & Leblanc, 2011) and a report (Heinemann, 2009) as evidence that the AAD-1 protein may be harmful.
MADGE (Aus)	• Opposes approval of the Application on the basis of the following claims: - There will be increased use of 2,4-D with concomitant development of 2,4-D resistant weeds and a detriment to the environment. - Although 2,4-D has been in use for years, there are alarming gaps in knowledge about its effects on human health. - Adverse effects were noted in two animals in the acute toxicity study. Further tests should have been conducted. • Believes that the full Application dossier should be made available to the public free of charge.
Sustainable Future Institute (NZ)	• Opposes approval of the Application • Argues that FSANZ favours the acceptance of the application based on political and economic international trade relationships, as opposed to proper assessment of public health. • Claims there is a lack of information on the safety of 2,4-D and harm that it could cause.

[6] NOTE by FSANZ: this same comment was made by Queensland Health in the 1st consultation and was explicitly addressed in the 2nd Assessment Report].

Submitter	Comments
GE Free New Zealand	• Opposes approval of the Application on the basis of the following claims: - FSANZ appears to favour the acceptance of the application based on political and economic international trade relationships, as opposed to proper assessment of public health. - There is good reason (such as evidence from the Flavr Savr tomato) to require the applicant to conduct meaningful larger generational feeding studies on the safety of the transgenic corn. - Adverse effects were noted in two animals in the acute toxicity study (ATS). Furthermore, with respect to the ATS, the assessment of no risk leads GE Free (NZ) to draw the conclusion that the lack of robust analysis is alarming as the sample size, length of time and number of studies is so small they do not meet the parameters of scientific testing. - The AAD-1 protein obtained from a bacterial system and used in several studies was produced in *Pseudomonas* not in *Sphingobium* (the source of the gene used for genetic modification) and hence may perform differently. - The Ministry of Agriculture and Forestry (MAF) in its 1st Assessment submission highlighted two instances of missing data[7]. - There are no data to show if transformation events could occur in the digestive tract between the engineered gene and similar species of bacteria. - The nature of the AAD-1 protein is unknown in the mammalian system and its effects on the liver or if it could alter the metabolic pathways. - The inability to be able to conclude that the AAD-*1* gene was not destroyed in 16 minutes because of its binding to the SGF protein requires further long term in vivo studies. - It appears that when a gene cassette is introduced into a cell it works differently to its straight isolate. - The lack of any nutritional impact either adverse or beneficial as stated is not valid as there have been no studies conducted. - There have been no long-term independent feeding studies. - A number of issues with the use of 2,4-D as a herbicide including: o No data to identify health and safety concerns either on the individual or the interaction between the two herbicides or their actions on the introduced engineered gene constructs. o Lack of any data to back up the assertions that the spraying to the maximum limit of 2,4-D on the crop food is safe o Analysis of the breakdown products of 2, 4-D has found that the metabolite 2,3,7,8 TCDD a dioxin can be produced (US EPA 1993). o Spraying of 2,4-D raises concerns for safety of the food as the growing conditions and usage cannot be assumed to be the same across all farms. o FSANZ has not set any levels for 2,4-D. o 2,4-D being a phenoxy based herbicide has been linked to soft tissue carcinoma, Non-Hodgkin's lymphoma, multiple myeloma and neurological problems.

[7] NOTE by FSANZ: MAF did not highlight 'missing data' in its 1st Assessment submission; it sought clarification on a) the natural degradation of 2,4-D and quizalofop-P-ethyl and b) the explanation of certain statistical results in the Compositional Analysis section of the Safety Assessment.

Submitter	Comments
	○ FSANZ has not followed Codex guidelines for considering potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. Levels of unexpected metabolites, new breakdown products, or stored toxic by-products in food corn are undefined.
Isla Burgess (Private)	• Opposes approval of the Application on the grounds that insufficient information is available about the unintended effects of this form of Genetic Manipulation (refers to website of The Nature Institute (http://www.natureinstitute.org/nontarget/) .
Renaee Churches (private)	• Opposes approval of the Application • Is concerned about the results of the acute oral toxicity study and suggests a repeat study with more animals over a longer time period.
Shirley Collins (Private)	• Opposes approval of the Application • States there should be no more GMO approvals until a) the report from the latest Review of Labelling Policy is written, and recommendations reviewed and implemented and b) we have positive proof that GM food is safe for humans to eat. • States that FSANZ has approved GM foods safe which other countries are declaring unsafe e.g. NK603, MON810, MON863 corn lines
Judy Cotton (Private)	• Opposes approval of the Application on the grounds that Dow AgroSciences Australia Pty Ltd, in their study, 071128, has not sought to investigate the reasons why a lesion was found in the stomach of one of the mice in the toxicity study and a dark area in the cerebrum of the brain in another.
Kristine Heather (Private)	• Opposes approval of the Application • Believes that there have been insufficient independent studies conducted to support the release of food derived from the corn line. • Expresses concern about the spread of seed into non-GM crops. • Expresses concern about eating chemicals that cannot be washed off.
Erica Hedberg (Private)	• Opposes approval of the Application
Lisa Hodgson (Private)	• Opposes approval of the Application on the grounds that independent studies have not been used in the safety assessment.
Fiona Hosford (Private)	• Opposes approval of the Application on the grounds that there is insufficient evidence (especially long-term) of the safety of the corn line.
Eva Knausenberger (Private)	• Opposes approval of the Application
Edith Stockdale (Private)	• Opposes approval of the Application on the grounds of health-related concerns with regard to the growing and consumption of such products as well as the contamination risk such products pose to other plants grown as food.

Submitter	Comments
Annie Stuart (Private)	• Opposes approval of the Application on the basis of the following arguments: - There is no substantial reason given for the need to introduce a genetically engineered 2,4-D tolerant corn variant. Is there a safer option available than the one proposed? - The herbicide spray regime and the potential residue load must be a factor in FSANZ's assessment of risk to public health and safety. - Introduction of GE corn and subsequent associated spraying regimes raise serious concerns for human health through exposure of workers, through the food chain, and through leaching into water supplies. - Independent studies have not been used in the safety assessment. - Consumers will not be able to make an informed choice about avoiding all products derived from the corn line. - Also lists points made in the Campaign letter – see below.
Jason Taylor (Private)	• Opposes approval of the Application on the grounds the safety assessment does not address environmental, accumulation or stacked downstream effects.
Phyllis Tichinin (Private)	• Opposes approval of the Application on the basis of the following arguments: - Large scale and intensive clinical and epidemiological studies over the last 30 years have clearly indicated that there is a firm link between pesticide exposures and Parkinson's, Non-Hodgkin's Lymphoma, learning disabilities, skin disorders, liver cancer and neurotoxic disorders. Approval of a line of a GM staple food with the express purpose of facilitating the routine application of a herbicide that has proven to have serious negative health impacts is contrary to the FSANZ mandate. - The dietary exposure modelling used by FSANZ is inadequate and will provide inaccurate appraisal of the potential health impacts of the increased dietary exposure to 2, 4 D. - What FSANZ is being asked to approve is the beginning of the slippery slope towards greater use of more toxic agricultural chemicals in pursuit of illusory gains in productivity. - There is no longer any doubt that genetically modified food is not the same as conventional food and a serious appraisal of all existing and in-process animal trials needs to be undertaken by FSANZ and made public before contemplating approval of this application.
Katharine White (Private)	• Opposes approval of the Application on the basis of the following arguments: - Weeds may develop resistance to the herbicide - The American Academy of Environmental Medicine has released a position paper on GM foods (http://www.aaemonline.org/gmopost.html) stating its concern about their safety. - Lack of independent data. - Concern that 2,4-D toxins cannot be washed out of the plant's genetic structure.

Submitter	Comments
Campaign Letter – the following 38 submitters made all or some of these comments: • Anna Archibald • Auckland GE Free Coalition • Sally Beale • Sonya Broccardo • Jon Carapiet • Carina Chambers • Carlos Chambers • Louis Chambers • Jacqueline Chartrand-Glenn • Charles Drace • Lisa Er • John Falls • Richard Gaddum • Sarah Hall • Emma Heke • Katie Hinton • Rebecca Hunter • Aaron Hosford • Reece Jensen • Ben Keet • Kiwi Organics • Martin Lempriere • Pete Maclennan • Christina McBeth • Timothy McBeth • Will McFarlane • Vivienne McFarlane • Johanna Metz • Jill Metz-Mayhead • Lucinda Sherratt • Annabel Sinclair-Thompson • Hilary Straume • Keith Symonds • Peter Volker • Silke Whittaker • Sally Williams • Soil & Health Association of New Zealand • Erin Young	• Opposes approval of the Application • There is inadequate safety evidence on the Herbicide Tolerant 2,4-D Corn Line. • This 2, 4-D corn is a potential risk to health. FSANZ is failing to maintain standards for a safe food supply for the citizens of Australia and New Zealand. • Independent safety studies published, after regulatory approvals of foods, in the last ten years show many problems with the introduction of GE into the food chain. • The application assessment does not address the safety of the consumer concerned about the huge range of metabolic, immune and digestive effects that might occur once the GM food is eaten. • No long term testing has been done. There is no data on its safety status; no maximum or minimum amounts of contaminants, residues, or other changes that may be present in plant food or that may be able to cause health problems. • This lack of safety data should put the application on hold until comprehensive safety studies are conducted that meet the International Codex parameters. • Ensuring dietary health is paramount. It is important that groups like the poor, elderly, children and health-challenged are assured that the food they eat will not worsen their health conditions. • The lack of diagnostic tools for transgenic detection by health practitioners is a severe omission in preserving and ensuring public safety. • Allergies to food products have risen over the last few years. It is no coincidence that the rise has coincided with the introduction of transgenic approvals. • There is no data about how 2, 4_D corn will interact, recombine, or transform with other GE foods. • Concern about cross-contamination of non-GM crops • New Zealand has an international reputation for being GE free and any erosion of this will have grave consequences for the NZ trading position.