22 February 2013
[02-13]

Approval Report – Application A1073

Food derived from Herbicide-tolerant Soybean Line DAS-44406-6

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Dow AgroSciences Australia Ltd and MS Technologies LLC seeking permission for food derived from soybean line DAS-44406-6 genetically modified to provide tolerance to the herbicides 2,4-dichlorophenoxyacetic acid (2,4-D), glufosinate ammonium and glyphosate.

On 25 October 2012, FSANZ sought submissions on a draft variation to Standard 1.5.2 and published an associated report. FSANZ received 68 submissions.

FSANZ approved the draft variation to the Standard on 13 February 2013. The COAG Legislative and Governance Forum on Food Regulation[1] (the Forum) was notified of FSANZ's decision on 20 February 2013.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting documents

The following document used to prepare this Report is available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1073food5541.cfm

SD1: Safety Assessment (at Approval)

1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Dow AgroSciences Australia Ltd and MS Technologies LLC on 27 April 2012. The Applicants requested a variation to Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code), to permit the sale and use of food derived from genetically modified (GM) soybean line DAS-44406-6, conferring tolerance to three herbicides.

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 is central to considering an application.

The safety assessment of soybean line DAS-44406-6 is provided in Supporting Document 1. No potential public health and safety concerns have been identified. Based on the data provided in the present Application, and other available information, food derived from soybean line DAS-44406-6 is considered to be as safe for human consumption as food derived from conventional soybean cultivars.

A decision has been made to approve the draft variation to Standard 1.5.2 to include food derived from herbicide-tolerant soybean line DAS-44406-6 in the Schedule.

2. Introduction

2.1 The Applicant s

Dow AgroSciences Australia Limited is a wholly owned subsidiary of The Dow Chemical Company and is a technology provider to the agricultural and food industries.

M.S. Technologies LLC is a United States of America-based trait and technology provider.

2.2 The Application

Application A1073 was submitted by Dow AgroSciences Australia Ltd and MS Technologies LLC on 27 April 2012. It sought approval for food derived from line DAS-44406-6 under Standard 1.5.2 – Food produced using Gene Technology.

Soybean line DAS-44406-6 is tolerant to the herbicides 2,4-dichlorophenoxyacetic acid (2,4-D), glufosinate ammonium and glyphosate. Tolerance to these respective herbicides is achieved by introducing the *aad-12* gene from the soil bacterium *Delftia acidovorans*, the *pat* gene from the soil bacterium *Streptomyces viridochromogenes* and the *2m epsps* gene from *Zea mays* (corn), encoding the AAD-12, PAT and EPSPS proteins respectively. Both the PAT and EPSPS proteins have been widely used to confer herbicide tolerance in a range of GM crop species. The AAD-12 protein has previously been assessed by FSANZ in Application A1046.

2.3 The current Standard

Pre-market approval is necessary before food derived from any genetically modified (GM) line may enter the Australian and New Zealand food supply. Approval of GM foods under Standard 1.5.2 is contingent on completion of a comprehensive pre-market safety assessment. Foods that have been assessed under the Standard, if approved, are listed in the Schedule to the Standard.

Standard 1.5.2 contains specific labelling provisions for approved GM foods. GM foods and ingredients (including food additives and processing aids from GM sources) must be identified on labels with the words ‘genetically modified’, if novel DNA or novel protein from an approved GM variety is present in the final food, or the food has altered characteristics. In the latter case, the Standard also allows for additional labelling about the nature of the altered characteristics.

2.4 Reasons for accepting the Application

The Application was accepted for assessment on the basis that:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected
- there was no other relevant matter to consider.

2.5 Procedure for assessment

The Application was assessed under the General Procedure.

2.6 Decision

The draft variation to Standard 1.5.2, as proposed following assessment, was approved without change.

The approved variation to the Standard is at Attachment A.

An Explanatory Statement is at Attachment B.

3. Summary of the findings

3.1 Risk assessment

The safety assessment of soybean line DAS-44406-6 is provided in SD1 and included the following key elements:

- a characterisation of the transferred genes, their origin, function and stability in the soybean genome
- the changes at the level of DNA and protein in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes
- the potential for the newly expressed proteins to be either allergenic or toxic in humans.

The assessment of soybean line DAS-44404-6 was restricted to food safety and nutritional issues. Any risks related to the release into the environment of GM plants used in food production, or the safety of animal feed or animals consuming feed derived from GM plants have not been addressed in this assessment.

No potential public health and safety concerns were identified.

On the basis of the data provided in the present Application, and other available information, food derived from soybean line DAS-44406-6 was considered to be as safe for human consumption as food derived from conventional soybean cultivars.

3.2 Risk management

3.2.1 Labelling

In accordance with the labelling provisions in Standard 1.5.2, food derived from soybean line DAS-44406-6 would have to be labelled as ‘genetically modified’ if it contains novel DNA or novel protein, or has altered characteristics. Food from DAS-44406-6 does not have altered characteristics.

Soybean DAS-44406-6 is intended primarily for use as a broad-acre commodity (field soybean) to produce products derived from cracked soybeans, and is not intended for vegetable or garden purposes where food-grade products may include tofu, soybean sprouts, soy milk, and green soybean (e.g. edamame). This latter type of soybean generally has a different size, flavour and texture to field soybean. The main food product from field soybean is refined oil. Processing during production means novel protein and novel DNA are not likely to be present in the oil and therefore it is unlikely to require labelling. Other products such as protein concentrate, protein isolate and textured flour are likely to contain novel protein and/or novel DNA and if so, would require labelling.

3.2.2 Detection methodology

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions has been formed by the Food Regulation Standing Committee - Implementation Sub-Committee to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM applications.

The EAG has indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA is sufficient data to be provided. Using this information, any analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the Applicants for DAS-44406-6 to satisfy the requirement for detection methodology in the FSANZ Application Handbook (Benjamini and Hochberg, 1995; FSANZ, 2011).

3.2.3 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

Public submissions were invited on a draft variation which was released for public comment between 25 October – 6 December 2012. Sixty-eight submissions were received, of which four supported the proposed variation. Forty-five submissions were closely based on a campaign letter prepared by GE Free New Zealand and promulgated via its website (http://press.gefree.org.nz/press/20121122.htm) on 22 November 2012. In addition, GE Free NZ sought, and was granted, a meeting with key FSANZ staff on Thursday 29 November 2012 to discuss a number of issues pertaining to Application A1073.

Of the remaining 19 submissions, one was prepared jointly by GE Free NZ and five other NGOs (MADGE Australia Inc., Gene Ethics, South Australia Genetic Food Information Network, FOODWatch) hereafter referred to as GEFNZ *et al.* This joint submission and the campaign letter have been considered separately below.

Some submissions indicated concern with the growing of GM crops e.g. the possibility of cross-pollination, the possible weediness of DAS-44406-6, impacts on the ecosystem, and co-existence of GM and non-GM crops. Some submissions raised issues to do with a perceived lack of consumer demand in relation to GM food, ethical concerns and trade concerns. Consideration of these issues is beyond the remit of FSANZ which deals primarily with the safety of food that is consumed.

Environmental issues are considered in Australia by the Office of the Gene Technology Regulator, and in New Zealand by the Environmental Protection Authority; it is also salient to note that there is currently no intention to grow soybean line DAS-44406-6 in either Australia or New Zealand.

As a result of the submissions one minor change has been made to the SD1.

3.2.3.1 General issues

Responses to eight general issues raised or implied, are provided in Table 1.

Table 1: Summary of general issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Concern with all GM food	Scott Baker, Jessica Harrison, Christina McBeth, Vincent Rowe, NZ Peasants Assoc, Physicians & Scientists for Global Responsibility	A number of studies were referred to in which it was claimed adverse effects from feeding GM food were shown. FSANZ has reviewed these studies and provided responses either in fact sheets (http://www.foodstandards.gov.au/consumerinformation/gmfoods/gmfactsheets) or in a table (http://www.foodstandards.gov.au/consumerinformation/gmfoods/gmtableofstudies.cfm). Written and video commentaries compiled by Michael Antoniou, Joseph Mercola and Jeffrey Smith, cited by one submitter (NZ Peasants Assoc), similarly base their arguments against the consumption of GM food on these same studies. These studies have also been evaluated by 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 identified serious flaws in the study methods or in the interpretation of the results.
Lack of faith in the FSANZ safety assessment	Shirley Collins, George Crisp, Jessica Harrison, Frank Rowson, Angus Wall, Bill Watson	A detailed description of the process used by FSANZ for the safety assessment of GM foods is available on the FSANZ website at http://www.foodstandards.gov.au/_srcfiles/GM%20Foods_text_pp_final.pdf In 2008, an external review of the FSANZ GM food safety assessment procedure was undertaken and identified a number of strengths (see FSANZ website at http://www.foodstandards.gov.au/consumerinformation/gmfoods/reviewofgeneticallym4394.cfm). See also response to Campaign letter on page 11.
Safety of food from animals fed GM soy	Jessica Harrison	Response is available on the FSANZ website at: Section 7.7: Safety Assessment of Genetically Modified Foods http://www.foodstandards.gov.au/_srcfiles/GM%20Foods_text_pp_final.pdf

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Labelling of GM food	Jessica Harrison, Alex Jones, FOODWatch	Responses are available on the FSANZ website at : Appendix 3: Safety Assessment of Genetically Modified Foods http://www.foodstandards.gov.au/_srcfiles/GM%20Foods_text_pp_final.pdf Labelling of GM Foods http://www.foodstandards.gov.au/consumerinformation/gmfoods/gmlabelling.cfm GM Labelling Review Report http://www.foodstandards.gov.au/newsroom/publications/gmlabellingreviewrep2460.cfm
General concern with the spraying of herbicides	Shirley Collins, Pauline Faulds, A Hodges, Alex Jones, Frank Rowson, NZ Peasants Assoc Physicians & Scientists for Global Responsibility	FSANZ does not have responsibility for assessing the environmental impacts or safe handling/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. Where a GM food is sprayed with chemicals (e.g. herbicides, insecticides) the resulting residue must meet the required Maximum Residue Limits in the Code (see discussion re Issue 3 on page 12).
Horizontal gene transfer to gut bacteria	Physicians & Scientists for Global Responsibility	This point is considered in a fact sheet on the FSANZ website available at http://www.foodstandards.gov.au/consumerinformation/gmfoods/gmfactsheets/gmfoodssafetyofinges5692.cfm
Allergies, including food allergies, have increased in New Zealand and other developed countries by epidemic proportions and this may be due to ingestion of GM foods.	Physicians & Scientists for Global Responsibility	The evaluation of a standardised set of data on the potential allergenicity of newly expressed protein is an integral part of the safety assessment of any GM food. This procedure is designed to identify and screen out newly expressed proteins that are considered likely to cause food allergy. On a case-by-case basis and depending on the evidence, FSANZ would consider withholding permission for a GM food that presented a likely food allergy risk. The increased prevalence of allergies in people eating Western diets is attributed to major allergens already in the food supply – milk, eggs and tree nuts, particularly peanuts. These commonly allergenic foods are not associated with GM commodities. There is no credible scientific basis to support the notion that food allergies are linked to the introduction of GM soybean or other GM crops. Allergy experts and those involved in the study of allergy generally do not regard this as a serious hypothesis.
Objection to submissions being called for in December	Alex Jones	The comment period for A1073 lasted for 6 weeks from late October to early December. The majority of the comment period was therefore in November and was completed well before Christmas.

3.2.3.2 Combined submission from GEFNZ et al.

The main focus of the submission was that DAS-44406-6 soybean has not been found safe for human consumption because the safety studies that were evaluated were insufficient. In response to this, FSANZ emphasises that in order for an Application to be accepted, it must comply with the data requirements set out in the *Application Handbook* (FSANZ, 2011).

In the case of GM foods, a large number of studies are specified which enable a detailed assessment by FSANZ of the nature of the genetic modification and its impact on the plant, the composition of the food, and the potential for any newly expressed proteins to be either allergenic or toxic to humans. The studies provided thus enable an assessment of the intended as well as any unintended changes to the food. The FSANZ data requirements, analysis of the data, and principles used in the safety assessment of GM foods are discussed in more detail under specific responses provided in the remainder of Section 3.2.3.

The Applicants for A1073 met all of the data requirements stipulated in the *Application Handbook* (FSANZ, 2011) for the safety assessment of GM food and, upon assessment of these data, FSANZ is satisfied that sufficient evidence has been provided to demonstrate the safety of the food.

The GEFNZ *et al*. submission went on to highlight three major areas of concern and these are addressed below. There were also additional points raised that require a response and these are considered under a separate 4th heading.

1. Compositional equivalence

The act of engineering new genes to confer tolerance to specific herbicides has significantly altered vital parameters in the chemical composition that in turn cause a change in the nutritional profile. This is evidenced by statistically significant differences found in a number of analytes.

Response: The main purpose of the compositional analyses is to determine if any unexpected changes in the composition of the food have occurred and to establish that substances that are nutritionally important or that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health. The levels of various constituents in the GM food are compared to the levels in an appropriate comparator using appropriate statistical analysis. Any identified statistically significant differences are then assessed against the range of natural variation to determine their biological relevance.

A number of significant differences in mean levels of 15 analytes encompassing minerals, amino acids and 'bioactives' were highlighted in the GEFNZ *et al*. submission. However, the submission considered the comparison-wise-P values rather than the False-Discovery-Rate (FDR)-Adjusted-P values despite the fact that the large number of contrasts made in the analyses leads to comparison-wise-P values having a high probability of falsely showing differences (Benjamini and Hochberg, 1995). For each analyte, five treatments (a non-GM control; unsprayed DAS-444-06-6; DAS-44406-6 sprayed with each of the three herbicides; DAS-44406-6 sprayed with all three herbicides) were considered. For 8 of the 15 analytes, the majority of the five DAS-44406-6 treatments did not show a significant difference from the control – thereby suggesting the results were due to chance and not to the genetic modification.

If the FDR-adjusted P values are considered (as in the FSANZ safety assessment), there are significant differences in seven not 15 of the analytes. For these FDR-adjusted P values the mean values of those analyte x treatment combinations showing a significant difference all fell within both the reference range and the literature range.

In FSANZ's experience, statistically significant differences in the levels of particular constituents are often noted in the compositional analyses. Such differences however are almost always consistent with the range of natural variation that occurs in all food and this was the case with DAS 44406-6. Therefore the measured level in DAS-44406-6 still falls within the range that is normally found in food and poses no greater risk, nutritionally or from a safety perspective, than soy food products produced from conventional soy varieties.

Such an approach, and the conclusion drawn, is consistent with the FSANZ safety assessment guideline (FSANZ, 2007), the Codex guidelines, and relevant FAO/WHO and OECD documents (see discussion under Issue 1 in Section 3.2.3.3).

2. Immune reactivity

The novel proteins in DAS-44406-6 would lead to the development of an allergic reaction, especially in those who consume soy products uncooked

Response: Humans do not consume uncooked soybeans as these contain potentially harmful toxicants and anti-nutritional factors that need to be inactivated through appropriate heat processing, including cooking (OECD, 2012).

The potential allergenicity of the novel proteins expressed in DAS-44406-6 was assessed using a weight of evidence approach based on data from a number of different studies. This approach is used because no single test is currently available which enables potential allergenicity of a novel protein to be determined. The studies that are used include bioinformatic analyses which assess the proteins similarity to known protein allergens, and studies which assess the structural properties of the proteins such as its susceptibility to enzymatic digestion and its heat stability. The source of the protein is also considered, i.e. whether the gene encoding the protein has been derived from a source known to be allergenic to humans. Proteins which have been derived from allergenic sources or which are significantly similar to known allergens are subject to further analyses involving the use of human sera or in some situations human skin testing (under appropriate medical supervision).

The three novel proteins expressed in DAS-44406-6 were subject to heat stability, digestibility and bioinformatic studies. These studies indicate that none of the expressed proteins are likely to be allergenic to humans.

There are no data to elucidate whether intact DNA could survive heating and pose an immunological problem.

Response: The consumption of DNA from any animal, plant and microbial food source is a natural part of the human diet. For many GM crops, the transgene (novel DNA) itself is already consumed as a component of traditional plant or microbial foods. Even if DNA may survive heating, once consumed, it is largely degraded in the gastro-intestinal tract (Hohlweq and Doerfler, 2001; Walsh *et al*., 2013). An adaptive immune-mediated response to ingested materials, if elicited, is directed only to protein and not DNA (Danilova, 2008).

3. OECD, Codex Alimentarius, EFSA

According to OECD, EFSA and Codex Guidelines, animal feeding studies should have been conducted with DAS-44406-6.

Response: Codex Guideline CAC/GL 45-2003 for the safety assessment of foods derived from recombinant-DNA plants (Codex, 2003) states that animal feeding studies “cannot be readily applied to testing the risks associated with whole foods” and may only be appropriate where “characterization of the food indicates that the available data are insufficient for a thorough safety assessment” (paragraph 11 of CAC/GL 45-2003). This guideline advocates the use of a comparative approach to identify differences between a new GM food and its conventional counterpart, with the identified differences becoming the focus of further assessment. The guideline recognises that traditional toxicological approaches may be useful in certain situations to evaluate some identified differences, for example, if a novel metabolite is expressed as a result of the genetic modification.

It does not, however, advocate the routine toxicological testing of whole GM foods, nor does it suggest that such testing should be used as a means to determine if statistically significant differences, identified through the compositional analyses, are biologically significant. The Guideline indicates that the biological relevance of statistically significant differences should be evaluated by comparing the measured level for the particular constituent against the levels typically found in the food in question. If the measured level is consistent with that normally found in food then the fact that it may be higher or lower than the level for that constituent in the control will be of no biological consequence to humans, given the variation that already exists in our diet.

The European Food Safety Authority (EFSA, 2008) has a similar position to that of Codex. The Organisation for Economic Co-operation and Development (OECD) does not have a guideline for determining when/if feeding studies should be conducted but does focus on the validity of a comparative assessment in determining the safety of a GM food (OECD, 1993).

In 2007, FSANZ convened an expert panel to develop guidance and recommendations on the role that whole-food animal feeding studies can play in the safety assessment of GM foods. The panel noted that whole-food animal feeding studies may be informative in some limited circumstances, but that any potential adverse health effects can generally be identified by a scientifically informed comparative assessment of the GM food against its conventional counterpart (see http://www.foodstandards.gov.au/consumerinformation/gmfoods/roleofanimalfeedings3717.cfm). This conclusion is reflected in the data requirements set out in the FSANZ *Application Handbook* (FSANZ, 2011) and is consistent with the principles expressed in the Codex and EFSA approaches.

As indicated in the safety assessment for DAS-44406-6, the compositional analyses did not indicate any compositional differences that were outside the range of natural variation. Therefore additional safety or nutritional assessment was not required and there is no reason to 'stop-the-clock' on the application in order to request animal feeding studies.

4. Other concerns

The occurrence of unintended effects/mutations (particularly production of harmful proteins) as a result of the transformation event.

Response: The genetic modification of a plant by the insertion of DNA sequences brings with it the possibility that unintended effects may occur. An unintended effect could be deleterious, beneficial or neutral with respect to health of the plant or the safety of the foods derived from it. Unintended effects are not restricted to the use of gene technology but can also occur with traditional plant breeding.

Many unintended effects are detected and eliminated in the early stages of research and development, particularly if they impact on the health or fitness of the plant. GM plant lines exhibiting adverse unintended effects are typically discontinued and would rarely, if ever, be considered for commercialisation. For example, one of the approaches to manage the problem of unintended effects is to select and discard plants with unusual or undesirable phenotypic and agronomic characteristics early in the breeding process. The practice of successive backcrossing in plants is also a strategy that is used to eliminate undesirable characteristics.

The safety assessment of GM foods involves methods to identify and detect unintended effects and procedures to evaluate their biological relevance and potential impact on food safety.

As no individual test can detect all possible unintended effects, or identify with certainty those relevant to human health, a variety of data and information is necessary to assess unintended effects. These data and information are considered together in order to assess the likelihood or otherwise of an unintended effect.

A thorough understanding of the genetic modification, as well as the characteristics and function of any novel proteins, is essential to ensure that the most appropriate comparative analyses are undertaken.

This identifies any important differences that may need to be investigated before the safety of a food can be established. Where unintended differences are observed, their biological significance is assessed. If the differences exceed natural variations in conventional foods, further assessment may be required.

> *DAS-44406-6 forage has been disallowed on the U.S. 2,4-D label. This raises the question of why animals are not allowed to eat DAS-44406-6 leaf material sprayed with 2,4-D.*

Response: Most herbicides, not just 2,4-D, have grazing and feeding restrictions stated on the label that limit the use of the crop for livestock feed. Livestock feeding following herbicide treatment is often restricted because data on residue levels in livestock which have consumed the crop are not available. The presence of such a restriction should therefore not be taken to mean that the residues are unsafe, but merely that there was an absence of data at the time of registration to support such use.

> *FSANZ should consider GE Free NZ submissions on A1046 and A1042*

Response: Application A1046[2] considered a GM corn line (DAS-68416-4) containing the same *aad-12* and *pat* genes expressed in DAS-44406-6. Application A1042[3] considered a GM soybean line (DAS-40278-9) containing an *aad-1* gene conferring tolerance to 2,4-D and 'fop' herbicides. The *aad-1* gene is closely related to the *aad-12* gene. The concerns raised in submissions made by GE Free NZ for applications A1042 and A1046 have been addressed in the Approval Reports prepared for those applications. The data provided in the dossiers for A1042 and A1046 further support the safety of the AAD-12 and PAT proteins expressed in DAS-44406-6 soybean.

3.2.3.3 Campaign letter

The campaign letter raised six major issues which are addressed below. These issues overlap to some extent with those raised in the GEFNZ *et al.* submission and the response is intended to further elucidate, rather than repeat, the comments in Section 3.2.3.2.

> *Issue 1 - FSANZ has not followed its legislated, Codex or OECD guidelines for risk assessment over significant changes of nutrient, protein, carbohydrates and anti-nutrients in A1073.*

Response: The conduct of all FSANZ GM safety assessments is subject to an approach outlined in a Guidance Document (FSANZ, 2007). The data requirements to support this approach are provided in the FSANZ *Application Handbook* (FSANZ, 2011). The approach and guidelines are based on scientific principles and guidelines developed through the OECD (OECD, 1993), FAO/WHO (FAO/WHO, 1991; FAO/WHO, 2000) and Codex (Codex, 2003; Codex, 2004).

[2] A1046 – available at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1046food4807.cfm
[3] A1042 – available at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1042food4758.cfm

No significant changes to levels of nutrients, proteins, carbohydrates or anti-nutrients in DAS-44406-6 were found, compared to levels in non-GM soybean varieties (see response to Compositional equivalence on page 8).

> *Issue 2 – Applicant information provided on safety is insufficient for assessment & approval into the food chain.*

A response to this issue is provided in the opening paragraph of the response to the GEFNZ *et al.* submission.

> *Issue 3 – There have been no feeding studies to show if there is risk from novel DNA or pesticides applied to the whole soybean.*

Response: Ingestion of novel DNA has been discussed in response #2 to the GEFNZ *et al*. submission. The issue of animal feeding studies has been discussed in response #3 to the GEFNZ *et al*. submission. However, Issue 3 above also suggests that feeding studies should be conducted with regard to ensuring the safety of food from crops that have been sprayed with a herbicide.

With regard to the application of herbicides, it is a requirement that the GM food safety assessment consider whether any novel metabolites are produced as a result of the genetic modification. Should novel metabolites be identified, then it is a requirement that appropriate toxicological studies be provided. In the case of soybean DAS-44406-6, spraying with glyphosate, 2,4-D or glufosinate ammonium does not result in the production of metabolites that are not also produced in conventional crops sprayed with the same herbicides and already used in the food supply. As a consequence, additional toxicological assessment is not required.

The use of agricultural and veterinary chemicals is subject to strict government regulation in most trading countries. In Australia and New Zealand, residues of agricultural and veterinary chemicals are prohibited in food (both GM and non-GM) unless they comply with specific limits referred to as Maximum Residue Limits (MRLs) - overseen in Australia by the Australian Pesticides and Veterinary Medicines Authority and in New Zealand by the Ministry for Primary Industries. The setting of MRLs ensures that residues of agricultural and veterinary chemicals are kept as low as possible and consistent with the approved use of chemical products to control pests and diseases of plants and animals. For further details see the FSANZ website at http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets/chemicalsinfoodmaxim5429.cfm.

MRLs pertaining to 2,4-D, glyphosate and glufosinate ammonium are given in Standard 1.4.2 of the Code and the Applicants have indicated that no change to any of these MRLs is being sought as a result of the intended herbicide use on DAS-44406-6.

> *Issue 4 – There is a lack of scientific data necessary to protect and maintain a safe food supply for the health and safety of people in Australia and New Zealand.*

Response: Each food, derived using gene technology, that is proposed for introduction to the Australian and New Zealand food supply must be assessed on a case-by-case basis. It is clear from the assessments that have been done to date that a large and comprehensive database of scientific data exists which supports the safety of such foods. All the GM foods that have been approved in Australia and New Zealand have also been approved by a number of other countries and at no stage have any of these assessments indicated that such foods pose a risk to human health and safety.

In relation to soybean DAS-44406-6, a large amount of scientific data was submitted by the Applicants, in accordance with the requirements set out in the Application Handbook. FSANZ is satisfied that sufficient scientific data exist (and were provided) to establish the safety of food derived from DAS-44406-6. This data conclusively shows that food derived from DAS-44406-6 is a safe as food derived from other soybean varieties.

> *Issue 5 – The reliance on the applicant's data has not shown impartiality, openness and accountability.*

Response: It is the responsibility of an Applicant to demonstrate the safety of the food and to supply FSANZ with all the data from scientific studies to prove this (see discussion in response to Issue 1, page.11). This procedure is consistent with that used to evaluate the safety of new chemicals and drugs and is standard practice for all regulatory agencies around the world. FSANZ experts review the scientific information and form their own conclusions from the results of the studies. FSANZ can, and does, request companies to undertake additional studies, where necessary. In addition, FSANZ complements the company data with information from the scientific literature, other applications and other government agencies.

All company supplied-studies must be adequately designed, conducted and documented in a manner that is consistent with the principles and practices of Good Laboratory Practice, and be accompanied by the raw data. This enables FSANZ scientists to be confident about the integrity of the study and to undertake an independent review of the data.

While relevant peer-reviewed published studies and other sources of information, if they exist and are of good quality, can be used to inform the safety assessment, they are not a substitute for company-supplied studies on the GM line of interest as they rarely address all the issues that are necessary to complete a safety assessment. Furthermore, it is typically not possible to undertake an independent review of the raw data that has been generated in such studies.

> *Issue 6 – FSANZ has not provided information to consumers that will enable better consumer choice. Over the last year there have been some highly concerning studies (e.g. Séralini et al., 2012[4]).*

Response: All FSANZ assessments, together with public submissions, are made available on the FSANZ website. Once a draft assessment has been completed all the company-submitted data (except any that has been determined to be confidential commercial information under the FSANZ Act 1991) is also made available on the FSANZ website. This ensures the FSANZ assessment process is both open and accountable.

FSANZ routinely monitors the ongoing scientific literature and will review any studies which purport to show adverse effects from GM foods or which are claimed by others to be evidence of adverse effects. A compilation of FSANZ's responses to such studies can be found on the FSANZ website at
http://www.foodstandards.gov.au/consumerinformation/gmfoods/gmtableofstudies.cfm

FSANZ is aware of the Séralini *et al*. paper which was published in September 2012. Since its publication, the study has attracted an unprecedented amount of criticism from individual academic experts in toxicology and pathology, independent expert groups, and regulatory agencies around the world.

[4] Séralini, G.-E.; Clair, E.; Mesnage, R.; Gress, S.; Defarge, N.; Malatesta, M.; Hennequin, D.; Spiroux de Vendemois, J. (2012). Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically-modified maize. *Food and Chemical Toxicology* 50: 4221 – 4231.

FSANZ completed a review of the paper and does not accept the interpretations and conclusions of the study authors. This review is available on the FSANZ website at http://www.foodstandards.gov.au/consumerinformation/gmfoods/gmfactsheets/responsetosralinipap5676.cfm. Other regulatory agencies have reached similar conclusions to FSANZ.

3.2.3.4 Other submissions

Responses to other issues raised specifically about the food safety of DAS-44406-6 and not addressed in Table 1 or under the responses to the GEFNZ *et al*. submission and the Campaign letter are provided below.

> *The 2m EPSPS and AAD-12 proteins have not been specifically assessed for allergenicity and toxicity (George Crisp).*

Response: Both proteins were assessed for potential allergenicity and toxicity (See Section 4 in SD1) according to the approach outlined in the FSANZ safety assessment guidelines (FSANZ, 2007). This approach is consistent with the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (Codex, 2003).

> *Concern about a lack of equivalence of proteins produced in a bacterial system and in the soybean plant (George Crisp).*

Response: The proteins used in the heat stability and digestibility studies were obtained from an *in vitro* GM bacterial system since it was not possible to obtain sufficient quantities of protein from DAS-44406-6. Sufficient testing was undertaken to demonstrate that each bacterially-produced protein was structurally and functionally equivalent to the protein expressed in the plant. The Applicants supplied extensive comparative data to confirm this (see Section.4.4.1 of the safety assessment).

> *The effect of heating on acrylamide production in the glyphosate-containing cooking oil produced from DAS-44406-6 soybean (Frank Rowson).*

Response: In a herbicide context, polyacrylamide is used as a spray drift reduction aid in many herbicide formulations, not just glyphosate formulations. A possible connection between glyphosate and production of acrylamide was first raised in two studies (Smith *et al*., 1997; Smith *et al*., 1996) which purported to show that polyacrylamide, in the presence of sunlight and glyphosate, could degrade to acrylamide. This was then further extended by some (e.g. Cummins, 2013) to suggest that cooking vegetables from plants sprayed with glyphosate would result in the further release of acrylamide.

The results of the two studies have subsequently been questioned (Ver Vers, 1999) as a result of the development of a more robust and accurate detection method for polymer analysis which showed that polyacrylamide does not degrade to acrylamide in the presence of glyphosate.

Additionally, there are two other points to consider

- The likelihood of glyphosate being present in processed oil is negligible.
- Even if glyphosate were present, the seed from which the oil was produced would have to meet the MRL for glyphosate (see also relevant MRL discussion under Issue #3 of the Campaign letter).

On this basis, there is low likelihood of acrylamide being a concern in cooking oil produced from DAS-44406-6 soybeans.

Concern with the levels of lectins and trypsin inhibitors found in DAS-44404-6 (Frank Rowson).

Response: Mean levels for both analytes fell well within the range shown in commercial, non-GM varieties of soybean. The levels of these substances were also unaffected by herbicide spraying. Also see response under the GEFNZ *et al*. submission (#1).

The endogenous allergen study submitted by the Applicant could be included in the safety assessment (NZ MPI).

Response: The Applicants submitted a study comparing the binding of protein extracts from DAS-44406-6 and 'Maverick' with sera from soybean allergic people. This type of study is not however a requirement in the FSANZ Application Handbook. FSANZ does not consider studies on endogenous allergens to be useful for GM food safety assessments for the following reasons:

- Based on current knowledge of food allergies and sensitization, the impacts of altered levels of endogenous allergens on human health are questionable and cannot be meaningfully interpreted, not even for those crops that are considered allergenic.
- Soybean-allergic consumers are able, because of mandatory labelling, to avoid all soybean-containing foods regardless of whether they are derived from a GM or a non-GM source.
- Recent studies of allergenic proteins in commercial soybean varieties already in the food supply (Houston *et al*., 2011; Panda *et al*., 2012; Stevenson *et al*., 2012) show that the levels vary considerably according to the variety of soybean (germplasm) and the environmental conditions in which it is grown. Consequently, small differences between a GM crop and its isogenic line grown under the same conditions would be considered of no biological significance.

Given that soybean-allergic individuals are protected through mandatory labelling of all soybean products, and the risks of developing allergy in the general population are not directly related to allergen exposure, FSANZ considers there is no scientific justification for including data on endogenous allergens in GM food safety assessments. The section on endogenous allergens has now been completely removed from the SD1.

People who consume DAS-44406-6 will unknowingly be ingesting the transgenes (PSGR)

Response: Under Standard 1.5.2 of the Australia New Zealand Food Standards Code any approved GM food, including that from DAS-44406-6 must be labelled with the words 'genetically modified' if any transgenes are present i.e. consumers can make an informed choice about whether or not they wish to consume the food.

3.3 Risk communication

FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media tools and the publication, *Food Standards News*. Subscribers and interested parties were also notified.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

Application A1073, including submissions received, is available on the FSANZ website.

4. Reasons for decision

The variation to the Code to permit the sale and use of food derived from herbicide-tolerant soybean line DAS-44406-6 in Australia and New Zealand was approved based on available evidence, for the following reasons:

- The safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce soybean line DAS-44406-6.

- Food derived from soybean line DAS-44406-6 is equivalent to that derived from the conventional counterpart and other commercially available soybean cultivars in terms of its safety for human consumption and nutritional adequacy.

- Labelling of food derived from soybean line DAS-44406-6 will be required in the ingredients list or in conjunction with the name of the food, if it contains novel DNA or novel protein.

- There were no measures that would be more cost-effective than a variation to Standard 1.5.2 and could achieve the same end.

4.1 Section 29

FSANZ had regard to the following matters under section 29 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweighed the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure

- there were no other measures that would be more cost-effective than a variation to Standard that could achieve the same end

- any relevant New Zealand standards

- any other relevant matters.

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.

4.1.1 Cost/benefit analysis

A consideration of the cost/benefit of approving the draft variation 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.

The points below list the effect that approving the draft would be expected to have on various sectors.

Consumers: Broader availability of imported soybean products as there would be no restriction on imported foods containing soybean line DAS-44406-6.

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

Government: Benefit that if soybean line DAS-44406-6 was detected in soybean imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of soybean line DAS-44406-6 would ensure no conflict with WTO responsibilities.

In the case of approved GM foods, monitoring is required to ensure compliance with the labelling requirements, and in the case of GM foods that have not been approved, monitoring is required to ensure they are not illegally entering the food supply. The costs of monitoring are thus expected to be comparable, whether a GM food is approved or not.

Industry: Importers of processed foods containing soybean derivatives would benefit as foods derived from soybean line DAS-44406-6 would be compliant with the Code, allowing broader market access and increased choice in raw materials.

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

Possible cost to food industry as some food ingredients derived from soybean line DAS-44406-6 would be required to be labelled.

As food from soybean line DAS-44406-6 has been found to be as safe as food from conventional cultivars of soybean, not preparing a draft variation would offer little benefit to consumers, as approval of soybean line DAS-44406-6 by other countries could limit the availability of imported soybean products in the Australian and New Zealand markets.

In addition, this option would result in the requirement for segregation of any products containing soybean line DAS-44406-6 from those containing approved soybean lines which would be likely to increase the costs of imported soybean-derived foods.

Also, not preparing a draft variation was considered likely to be inconsistent with Australia's and New Zealand's WTO obligations.

Based on the conclusions of the safety assessments, the potential benefits of approving the variation outweighed the potential costs.

4.1.2 Other measures

There were no measures that could achieve the same result other than an amendment to Standard 1.5.2.

4.1.3 Relevant New Zealand standards

Standard 1.5.2 applies in New Zealand.

4.1.4 Any other relevant matters

The Applicants submitted a food and feed safety and nutritional assessment summary for DAS-44406-6 to the US Food and Drug Administration in September 2011 and also requested a Determination of Nonregulated Status for DAS-44406-6, including all progeny derived from crosses between DAS-44406-6 and other soybean lines, from the Animal and Plant Health Inspection Service of the US Department of Agriculture in August 2011.

Applications have also been submitted to Argentina, Canada, Korea, European Union (EU27), Switzerland, Brazil, Japan, Uruguay and South Africa.

The Applicants have indicated that submissions are likely to be made to a number of additional governmental regulatory agencies for import clearance and production approval including, but not limited to, those in Taiwan, China and Mexico.

It is the Applicants' intention that soybean line DAS-44406-6 be commercially cultivated predominantly in North America. There is currently no intention to apply for approval to cultivate this line in either Australia or New Zealand.

Such cultivation 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 in Australia and the Environmental Protection Authority in New Zealand, before commercial release in either country could be permitted.

4.2 Addressing FSANZ's objectives for standards setting

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

4.2.1 Protection of public health and safety

Food derived from soybean line DAS-44406-6 has been assessed according to the safety assessment guidelines prepared by FSANZ (2007).

No public health and safety concerns were identified in this assessment. Based on the available evidence, including detailed studies provided by the Applicants, food derived from soybean line DAS-44406-6 is considered as safe and wholesome as food derived from other commercial soybean cultivars.

4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

In accordance with existing labelling provisions, food derived from soybean line DAS44406-6 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein.

4.2.3 The prevention of misleading or deceptive conduct

The requirement for detection methodology (see Section 3.2.2) is designed to address this objective.

4.2.4 Subsection 18(2) considerations

FSANZ has also had regard to the objectives set out in subsection 18(2):

- *The need for standards to be based on risk analysis using the best available scientific evidence*

  FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex General Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2004). Based on these principles, the risk analysis undertaken for soybean DAS-44406-6 used the best scientific evidence available. The Applicants submitted to FSANZ, a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the Applicants, other available resource material including published scientific literature and general technical information was used in the safety assessment.

- *The promotion of consistency between domestic and international food standards*

  This is not a consideration as there are no relevant international standards.

- *The desirability of an efficient and internationally competitive food industry*

  The inclusion of GM foods in the food supply, providing there are no safety concerns, allows for innovation by developers and a widening of the technological base for the production of foods. Soybean line DAS-44406-6 is a new food crop designed to provide growers in a number of countries around the world with an alternative weed management strategy.

- *The promotion of fair trading in food*

  The cost/benefit analysis in Section 4.1 lists a number of considerations that address fair trading with respect to soybean line DAS-44406-6.

- *Any written policy guidelines formulated by the Ministerial Council*

  For GM foods, there are no relevant ministerial guidelines.

4.3 Implementation

The variation will take effect on gazettal.

5. References

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Attachments

A. Approved variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

Attachment A – Approved variation to the *Australia New Zealand Food Standards Code*

Food Standards (Application A1073 – Food derived from Herbicide-tolerant Soybean DAS-44406-6) 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

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Application A1073 - Food derived from Herbicide-tolerant Soybean DAS-44406-6) Variation*

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

This variation commences on **the date of gazettal**.

SCHEDULE

[1] Standard 1.5.2 is varied by inserting in numerical order in the Schedule

“

7.13	Food derived from herbicide-tolerant soybean line DAS-44406-6

”

Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in *the Australia New Zealand Food Standards Code* (the Code).`

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1073 which seeks permission for the sale and use of food derived from herbicide-tolerant soybean line DAS-44406-6. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to a Standard.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation[5], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act 2003.*

2. Purpose and operation

As it is not listed in the Schedule to Standard 1.5.2, food derived from soybean line DAS-44406-6 is not currently permitted for sale or use in food. This variation permits the sale, or use in food, of food derived from soybean line DAS-44406-6.

3. Documents incorporated by reference

This variation does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1073 included one round of public consultation following an assessment and the preparation of a draft variation to the Standard and associated report. Submissions were called for on 25 October 2012 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Standard 1.5.2 is likely to have a minor impact on business and individuals.

[5] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

This item adds food derived from soybean line DAS-44406-6 into the Schedule to Standard 1.5.2.