



4 October 2011
[18-11]

APPLICATION A1041

FOOD DERIVED FROM SDA SOYBEAN LINE

MON87769

APPROVAL REPORT

Executive Summary

Main points:

- **The Application seeks approval for food derived from soybean that has been genetically modified to produce stearidonic acid (SDA), an omega-3 fatty acid, in the seeds of the plant.**
- **The Applicant states that SDA soybean oil can partially replace the use of conventional soybean oil in various food applications and will contribute to dietary intakes of omega-3 fatty acids.**
- **It is anticipated that SDA soybean would be grown in North America in limited acreage, and would be identity-preserved. It is not intended for cultivation in Australia or New Zealand.**
- **Once approved and commercialised overseas, food derived from SDA soybean could enter Australia and New Zealand through imported products.**
- **The Safety Assessment and a separate Nutrition Assessment did not identify any potential public health and safety concerns.**
- **Issues raised in submissions have been addressed in this report.**
- **A draft variation to Standard 1.5.2 Food produced using Gene Technology giving approval to SDA soybean has been prepared.**
- **In accordance with GM labelling laws, food derived from SDA soybean must be labelled, including the refined oil, due to the altered nutrient profile.**

Purpose

An Application was received from Monsanto Australia Limited on 20 January 2010, seeking amendment 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 soybean line MON87769. This variety of soybean has been genetically modified (GM), to produce stearidonic acid (SDA), an omega-3 fatty acid.

The novel trait in MON87769 soybean is conferred by the expression of two introduced genes encoding enzymes involved in fatty acid metabolism. When simultaneously expressed in the seed, the enzymes convert linoleic acid (LA) to alpha linolenic acid (ALA) and gamma linolenic acid (GLA), which are in turn converted to SDA. As a result, refined oil produced from MON87769 soybean contains approximately 20–30% SDA. Conventional soybean plants lack the key enzyme required for the production of SDA.

In mammals, there is only poor conversion of ALA, a common dietary constituent, to the long-chain omega-3 polyunsaturated fatty acid, eicosapentenoic acid (EPA). SDA, normally present in only a few foods, is one of the metabolic intermediates in the omega-3 pathway between ALA and EPA. As SDA is one metabolic step closer to EPA, the rate-limiting conversion of ALA to SDA has been overcome.

Fish and marine oils are typically the most significant dietary sources of EPA and docosahexaenoic acid (DHA), however these fatty acids are susceptible to oxidation and prone to undesirable odours and taste. SDA soybean oil is more stable and can be used in wider food applications. The anticipated food uses of SDA soybean oil are in a variety of packaged foods such as baked goods, breakfast cereals and bars, grain products, pastas and milk products. Soybean meal derived from MON87769 is similar in composition to meal from other soybean varieties and can be used as conventional meal.

MON87769 soybean is intended for low-acreage cultivation in North America, and will be grown, transported and processed using an identity preserved system. Approval in the Code is necessary before any food products derived from this line may enter the Australian and New Zealand markets.

This Application was assessed under the Major Procedure, which includes two rounds of public consultation. The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in s18 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), is the protection of public health and safety. Accordingly, the safety assessment formed the central component of this Application.

Safety Assessment

FSANZ completed a comprehensive safety assessment of food derived from MON87769 soybean (**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; (iii) the composition of MON87769 soybean compared with that of conventional soybean varieties; and (iv) a consideration of the nutritional impact of SDA-rich soybean oil. No public health and safety concerns were identified in this assessment. On the basis of the available evidence, which includes detailed studies provided by the Applicant and other relevant information, food derived from SDA soybean line MON87769 is as safe as food derived from conventional soybean varieties.

Nutrition Assessment

A separate nutrition assessment considered the dietary effects of SDA soybean MON87769 in more detail (**Supporting Document 2**). SDA is normally consumed in small quantities in the Australian and New Zealand diets, and is metabolised in the same way as other fatty acids that are more abundant in the diet. Data from several clinical trials showed that dietary SDA (3.7 g/day in supplement form) results in statistically significant increases in EPA levels in blood plasma and erythrocytes, compared with a placebo group.

The level of *trans* fatty acids in SDA soybean oil is marginally higher than in conventional soybean oil, however the levels are comparable to other commonly consumed vegetable oils. Overall, the introduction of MON87769 soybean into the food supply would not be expected to have an impact on overall intakes of *trans* fats in the Australian and New Zealand diets.

Labelling

In the case of GM food, labelling seeks to address the objective set out in paragraph 18(1)(b) of the FSANZ Act, that is, the provision of adequate information relating to food to enable consumers to make informed choices.

If approved, food derived from MON87769 soybean will be required to be labelled as 'genetically modified', irrespective of whether novel DNA or protein are present in the final food due to the altered nutrient profile. This means that labelling of SDA soybean oil as 'genetically modified' would be required because of the changes in the composition of the oil.

FSANZ considers that general mandatory labelling requirements for GM foods would provide consumers with adequate information about this product to enable an informed choice. In addition, a voluntary claim relating to polyunsaturated fatty acid content would be permitted.

Impact of regulatory options

Following satisfactory completion of the safety and nutrition assessments, two regulatory options were considered: (1) no approval; or (2) approval of food derived from MON87769 soybean. Analysis of the potential costs and benefits of each option on affected parties (consumers, the food industry and government) concluded that option 2, approval of this Application is the preferred option. Under option 2, the potential benefits to all sectors outweigh the costs associated with the approval.

Assessing the Application

In assessing this Application, FSANZ has had regard to the following matters as prescribed in section 29 of the FSANZ Act:

- whether costs that would arise from an amendment to the Code approving food derived from soybean line MON87769 do not outweigh the direct and indirect benefits to the community, Government and industry that would arise from the development or variation of the food regulatory measure
- there are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same end
- there are no relevant New Zealand standards
- any other relevant matters.

Decision

To approve the variation to Standard 1.5.2 – Food produced using Gene Technology, to include food derived from soybean line MON87769 producing stearidonic acid, in the Schedule.

Reasons for Decision

On the basis of the available scientific evidence, a variation to the Code giving approval to the sale and use of food derived from SDA soybean line MON87769 in Australia and New Zealand is proposed for the following reasons:

- the safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce SDA soybean MON87769
- food derived from SDA soybean MON87769 is equivalent to commercially available soybean varieties in terms of its safety for human consumption and nutritional adequacy
- labelling will be required for all foods derived from SDA soybean MON87769 due to the altered nutrient profile
- a regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is a variation to the Code, and
- there are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same end.

Consultation

Submissions were invited on the 1st Assessment Report over a period of nine weeks; nine submissions were received. Submissions were invited on the 2nd Assessment Report over a period of four weeks; six submissions were received. A summary of these is provided in this Report at **Attachment 2**.

FSANZ considered submissions received in the consultation periods and addressed issues, particularly those relevant to the safety of food derived from MON87769 soybean. Submissions on the 2nd Assessment were used to make a decision on the draft variation (**Attachment 1**). Additional or amended information was incorporated into the Approval Report and Supporting Documents where necessary.

CONTENTS

INTRODUCTION	2
1. THE ISSUE / PROBLEM.....	2
2. CURRENT STANDARD	3
2.1 <i>Background</i>	3
2.2 <i>Overseas approvals</i>	3
3. OBJECTIVES	3
4. ASSESSMENT QUESTIONS	4
RISK ASSESSMENT	4
5. RISK ASSESSMENT SUMMARY.....	4
5.1 <i>Safety assessment process</i>	4
5.2 <i>Outcomes of the Safety Assessment</i>	5
5.3 <i>Outcomes of the Nutrition Assessment</i>	6
RISK MANAGEMENT	6
6. LABELLING	6
7. DETECTION METHOD	8
8. OPTIONS	8
8.1 <i>Option 1 – reject the Application</i>	8
8.2 <i>Option 2 – approve a draft regulatory measure</i>	8
9. IMPACT ANALYSIS	9
9.1 <i>Affected Parties</i>	9
9.2 <i>Benefit Cost Analysis</i>	9
9.3 <i>Comparison of Options</i>	10
COMMUNICATION AND CONSULTATION STRATEGY	11
10. COMMUNICATION	11
11. CONSULTATION	11
11.1 <i>Public consultation</i>	11
11.2 <i>General issues</i>	11
11.3 <i>Specific issues</i>	12
11.4 <i>World Trade Organization</i>	16
CONCLUSION	16
12. CONCLUSION AND DECISION.....	16
12.1 <i>Reasons for Decision</i>	16
13. IMPLEMENTATION AND REVIEW	17
REFERENCES	17
ATTACHMENT 1 - DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE	18
ATTACHMENT 2 - SUMMARY OF PUBLIC SUBMISSIONS ON 2 ND ASSESSMENT REPORT	20

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/applicationa1041food4746.cfm>

SD1: Safety Assessment Report: Application A1041 – Food Derived from MON87769 soybean – Approval

SD2: Nutrition Assessment Report: Application A1041 – Food Derived from MON87769 soybean – Approval

INTRODUCTION

Monsanto Australia Limited submitted an Application on 20 January 2010, seeking approval for food derived from soybean line MON87769 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

Soybean line MON87769 has been genetically modified (GM) to produce stearidonic acid (SDA), an omega-3 fatty acid. The trait is conferred by the expression of two introduced genes encoding the enzymes: delta-6 desaturase from *Primula juliae* (Pj.Δ6D) and delta-15 desaturase from *Neurospora crassa* (Nc.Δ15D). These enzymes are involved in fatty acid metabolism of naturally occurring substrates, linoleic acid (LA) and alpha linolenic acid (ALA). Conventional soybean plants lack a delta-6 desaturase gene, a minimal requirement for the production of SDA, and therefore oil from conventional soybeans does not contain SDA. The seed-specific expression of both enzymes increases the biochemical flux to SDA from both ALA and gamma linolenic acid (GLA). As a result, refined oil produced from MON87769 soybean contains approximately 20–30% SDA.

In mammals, SDA is a metabolic intermediate in the production of the long-chain omega-3 polyunsaturated fatty acids (LCPUFA), eicosapentenoic acid (EPA) and docosahexaenoic acid (DHA), from ALA. Although ALA is a common dietary constituent, its conversion to SDA in the body is the rate limiting step in the omega-3 pathway. Studies have shown that consumption of SDA, either in foods or in supplement form, can lead to higher levels of EPA in body tissues, compared with ALA.

Fish and marine microalgae are typically considered to be the most significant dietary sources of essential long-chain omega-3 fatty acids. However, due to their naturally high EPA and DHA content, fish and algal oil products are susceptible to oxidation and prone to impart undesirable (rancid) odours and taste to foods. Compared with fish oils, the Applicant claims that SDA soybean oil is more stable and can be used in wider food and animal feed applications. The anticipated food uses of SDA soybean oil are in a variety of packaged foods such as baked goods, breakfast cereals and bars, grain products and pastas, sauces, soups and milk products. Due to the high PUFA content, SDA soybean oil derived from MON87769 is not considered suitable for high temperature frying, and would require modification for the manufacture of table spreads or margarines. Soybean meal derived from MON87769 is similar in composition to meal from other soybean varieties and can therefore be used in a manner similar to conventional soybean meal.

This Application was assessed as a Major Procedure, involving two rounds of public consultation. The 1st Assessment Report included a full scientific evaluation of food derived from MON 87769 soybean according to FSANZ guidelines (FSANZ, 2007) to assess its safety for human consumption. This report was released in November 2010 and public comment was sought on the safety assessment (**Supporting Document 1**) and nutrition assessment (**Supporting Document 2**). Based on comments received in submissions, FSANZ prepared a draft variation to Standard 1.5.2 and associated 2nd Assessment Report, which included minor amendments to the Nutrition Assessment. Following the second round of consultation, public comments were considered in making a decision on the draft variation included in this Approval Report.

1. The Issue / Problem

The Applicant has developed genetically modified soybean line MON87769, which produces SDA-rich soybean oil. The SDA soybean oil is intended as a plant-based source of omega-3 fatty acids and can be used in a range of food applications. Pre-market approval is necessary before this product may enter the Australian and New Zealand food supply.

A variation to the Code listing food derived from MON87769 soybean in Standard 1.5.2 must be approved by the FSANZ Board, and that decision subsequently be notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). Variations to the Code may only be gazetted and registered as a legislative instruments once the Ministerial Council process has been finalised.

MON87769 soybean is intended for small acreage cultivation in North America and will be identity preserved¹. Before its release into commercial markets, the Applicant is seeking regulatory approval for MON87769 soybean in a number of trading countries, including Australia and New Zealand. This is necessary because once it is cultivated on a commercial-scale, processed soybean products imported into Australia and New Zealand could contain components derived from MON87769 soybean.

2. Current Standard

2.1 Background

Approval of GM foods under Standard 1.5.2 is contingent upon completion of a comprehensive pre-market safety assessment. Foods that have been assessed under the Standard, if approved, are currently listed in the Schedule to the Standard.

2.2 Overseas approvals

Submissions on soybean line MON87769 have been made to the appropriate agencies for food, feed and environmental approvals in the United States (Food and Drug Administration, Department of Agriculture – Animal and Plant Health Inspection Service) and Canada (Health Canada and the Canadian Food Inspection Agency). An import submission for food and feed use has been made to the European Food Safety Authority. In addition, regulatory submissions have or will be made to government agencies in Japan (Ministry of Health, Labour and Welfare, Ministry of Agriculture, Forestry and Fisheries), China (Ministry of Agriculture), and Korea (Rural Development Administration, Korea Food and Drug Administration). In due course, further notifications will be made to countries that import significant quantities of American-grown soybean and products, and do not have a formal regulatory review process for biotechnology-derived crops.

The Applicant provided an update on the process of obtaining global regulatory approval for MON87769 soybean in February 2011, and recently confirmed there has been no change in its status, although a decision in the United States is expected in the near future.

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.

¹ This means that seed harvested from MON87769 soybean will be strictly maintained as a segregated product from other commercial soybean.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Assessment questions

In completing the assessment of this Application, the following questions were addressed:

- (i) Based on information provided by the Applicant on the nature of the genetic modification, the molecular characterisation, the characterisation of the novel proteins, the compositional analysis and consideration of the nutritional issues, is food derived from SDA soybean line MON87769 as safe for human consumption as food derived from conventional varieties of soybean?
- (ii) Is other information available, including from the scientific literature, general technical sources, independent scientists, other regulatory agencies, international bodies and the general community, that should be taken into account in this assessment?
- (iii) Are there any other considerations that would influence the outcome of this assessment?

RISK ASSESSMENT

Food derived from SDA soybean line MON87769 was evaluated according to FSANZ safety assessment guidelines (FSANZ, 2007), and in a separate nutrition assessment (**Supporting Documents 1 and 2**). The summary and conclusions from these assessments 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 these assessments.

5. Risk Assessment Summary

5.1 Safety assessment process

The safety assessment of MON87769 soybean included the following key elements: a characterisation of the transferred genes, their origin, function and stability in the soybean genome; the changes at the level of DNA, protein and in the whole food; detailed compositional analyses; evaluation of intended and unintended changes; and the potential for the newly expressed proteins to be either allergenic or toxic in humans.

The assessment of MON87769 soybean was confined solely to food safety and nutritional issues, but excluded consideration of any purported health or nutritional benefits arising from the consumption of long-chain omega-3 fatty acids.

In addition, the assessment did not address any potential 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.

5.2 Outcomes of the Safety Assessment

MON87769 soybean contains two novel genes, *Pj.D6D* and *Nc.fad3*. These encode respectively a delta-6 desaturase from the plant *P. juliae*, and a delta-15 desaturase from the fungus *N. crassa*. Detailed molecular analyses indicated that one copy of each gene has been inserted at a single site in the soybean genome. The *Pj.D6D* and *Nc.fad3* genes are stably inherited from one generation to the next.

The two novel proteins expressed in MON87769 soybean, Pj.Δ6D and Nc.Δ15D, are members of a large family of fatty acid desaturases that occur across the plant and animal kingdoms and are naturally part of human diets. Pj.Δ6D and its homologues occur widely in edible plants commonly used as foods, herbal medicines or dietary supplements, including echium (*Echium plantagineum*), borage (*Borago officinalis*) and evening primrose (*Oenothera* spp.). The source plant Primrose is itself used both as a food and herbal medicine. Humans are also likely to have been exposed to delta-6 desaturase from the consumption of fresh water fish such as rainbow trout (*Oncorhynchus mykiss*). The source of Nc.Δ15D, *N. crassa*, is ubiquitous in the environment and is used to manufacture food in a variety of world regions and diets. Delta-15 desaturases are found mainly in fungi and plants, including for example cruciferous vegetables.

The proteins are expressed at low levels in MON87769 soybean seeds. The mean concentration of Pj.Δ6D and Nc.Δ15D in harvested seed is 1.8 and 10.0 μg/g dry weight, respectively. The proteins expressed in the soybean are the expected size and amino acid sequence, are immunoreactive to the corresponding antibodies, are not glycosylated, and exhibit the expected functional enzyme activity.

Bioinformatic studies with Pj.Δ6D and Nc.Δ15D confirmed the absence of any biologically significant amino acid sequence similarity to known protein toxins or allergens. Digestibility studies demonstrated that both proteins would readily degrade in the human digestive tract, similar to other dietary proteins. Separate oral toxicity studies on Pj.Δ6D and Nc.Δ15D in mice confirmed the absence of acute toxicity. Taken together with the history of previous dietary exposure, the evidence indicates that neither protein is toxic, nor likely to be allergenic in humans.

Compositional analyses of SDA soybean MON87769, the non-GM control, and ten commercially available soybean varieties grown under the same conditions, established that, except for the production of SDA, MON87769 soybean seed is comparable to other commercial soybeans. As anticipated, there are other more minor changes in fatty acid composition, although the levels are within the reference range for soybean and, for some analytes, occur at similar levels in other commonly consumed oil-seed crops. For other key components, there are no biologically significant compositional differences in MON87769 compared with conventional soybean.

The safety of SDA soybean oil is further supported by the results of a published 90-day/one generation reproductive toxicity study in rats and other feeding studies with soybean meal; no adverse findings were noted in any of the animal studies. The genetic modification, resulting in the accumulation of SDA and other more minor changes in fatty acid composition therefore does not adversely affect the nutritional adequacy of the food.

Additional allergenicity studies found no difference in immunoglobulin binding between soybean MON87769, the non-GM control and 24 commercial soybean varieties, which indicates that the levels of endogenous soybean allergens have not significantly changed as a result of the genetic modification in MON87769 soybean. The introduction of SDA soybean oil derived from MON87769 into the food supply for specific food applications requiring omega-3 fatty acids, would therefore not raise any food safety concerns.

5.3 Outcomes of the Nutrition Assessment

The nutritional implications of the production of SDA in the seeds of MON87769 soybean plants, and other consequential changes in fatty acids, were examined in the nutrition assessment (SD2). The assessment compared the effects of consumption of SDA-rich oils and EPA-rich oils on EPA levels in blood plasma and erythrocytes. The effect of SDA-rich and EPA-rich oils on the omega-3 index² was also considered.

The consumption by adults of SDA at levels of 3.7 g/day or more resulted in statistically significant increases in EPA in blood plasma and erythrocytes, compared with a placebo group. The conversion of SDA to EPA in these tissues was relatively complete. These effects were observed after eight weeks of supplementation. There was no measured effect of SDA on DHA levels in the blood.

The relative effectiveness of conversion of dietary SDA to EPA in plasma and erythrocytes ranges from 17-30%. The relative effectiveness of conversion of SDA in SDA soybean oil to EPA in plasma and erythrocytes is likely to be at the lower end of this range; although, as with all sources of SDA, it is likely to be subject to variation depending on a number of individual and concurrent dietary factors.

While SDA is normally consumed in small quantities in the Australian and New Zealand diets, the available evidence indicated that there is unlikely to be any adverse effects from an increase in the consumption of SDA, up to 4.2 g/day. In addition, although the TFA content in SDA soybean oil is marginally higher than in conventional soybean oil, the level (0.67 g TFAs per 100 mL) is well within the range found in commonly consumed edible oils (0-1.8 g TFAs per 100 mL). The introduction of SDA soybean oil into the food supply is therefore unlikely to increase overall TFA intakes in Australia and New Zealand above current levels.

5.4 Conclusions

No potential public health and safety concerns were identified in the assessment of SDA soybean MON87769. On the basis of the data provided in the Application, published references and other relevant information, food derived from SDA soybean MON87769 is considered as safe for human consumption as that from commercially available soybean varieties. SDA-rich soybean oil is a dietary source of omega-3 fatty acids.

RISK MANAGEMENT

6. Labelling

In accordance with the mandatory labelling provisions of Standard 1.5.2 (clause 5), food derived from SDA soybean MON87769, if approved, will be required to be labelled as 'genetically modified'.

² The omega-3 index is the combined proportion of EPA and DHA in erythrocyte membranes, expressed as a per cent of total fatty acids, and is correlated with cardiac membrane EPA and DHA (Harris *et al.* 2004).

Whole soybeans and processed fractions such as soybean meal, protein isolate, and lecithin contain plant DNA or protein and will therefore require mandatory labelling for the presence of novel DNA or novel protein in the final food. Refined soybean oil produced from MON87769 will also require labelling as 'genetically modified' because of the significantly altered fatty acid composition (refer to paragraph 4(1)(b) of Standard 1.5.2). In addition, the SDA content in oil produced from MON87769 will likely lead to specific food applications that differ from uses of conventional soybean oil (refer to paragraph 7(d) of Standard 1.5.2).

As a result of the nutrition assessment, FSANZ has concluded that SDA soybean oil produced from MON87769, has the potential to be used as a source of omega-3 fatty acids. Subclause 13(3) of Standard 1.2.8 – Nutrition Information Requirements states that a nutrition claim must not be made in relation to the omega-3 fatty acid content of a food, unless the food contains no less than 200 mg alpha-linolenic acid or 30 mg total eicosapentaenoic acid and docosahexaenoic acid, per serving. Stearidonic acid, being a different omega-3 fatty acid, does not meet this requirement. Therefore, current requirements in the Code would not allow a nutrition claim about the omega-3 fatty acid content for food derived from SDA soybean MON87769. This is consistent with omega-3 claim requirements for any conventional (non-GM) foods that provide a dietary source of stearidonic acid, for example, fish.

Food derived from MON87769 soybean may meet the requirements for making a polyunsaturated fatty acid claim with respect to its SDA content. Subclause 12(1) of Standard 1.2.8 permits a claim where the:

- total of saturated fatty acids and *trans* fatty acids comprises no more than 28% of the total fatty acid content of the food, and
- fatty acid in respect of which the nutrition claim is made comprises no less than 40% of the total fatty acid content of the food.

Where a polyunsaturated fat nutrition claim is made in accordance with the definition of polyunsaturated fatty acids (PUFA)(clause 1), the polyunsaturated fatty acid content (subclause 5(7) in Standard 1.2.8) must be declared in the nutrition information panel. Voluntary polyunsaturated fatty acid claims also trigger the requirement to declare *trans* fatty acids and monounsaturated fatty acids in the nutrition information panel (subclause 5(4)).

In the case of GM food, labelling is intended to address the objective set out in paragraph 18(1)(b) of the FSANZ Act; the provision of adequate information relating to food to enable consumers to make informed choices. For this reason, FSANZ has considered the need for an additional labelling statement to inform consumers of the altered nutrient profile. In the 1st Assessment Report, FSANZ noted that consumers are more likely to have a better understanding of the general terms 'omega-3' and 'saturated fats' than to have an understanding of the differences between individual fatty acids. As such, mandatory labelling that refers to specific fatty acids, such as stearidonic acid, could be confusing to consumers.

A mandatory statement to the effect that the food has been genetically modified to contain stearidonic acid as an omega-3 fatty acid, would be inconsistent with omega-3 claim conditions in Standard 1.2.8. As outlined above, clause 13 of Standard 1.2.8 requires a serving of the food carrying an omega-3 nutrition claim to contain minimum amounts of ALA or EPA and DHA, whereas a mandatory labelling statement for oil derived from MON87769 would simply inform consumers of the presence of SDA, irrespective of the amount in the food.

A mandatory statement could also imply that the food contributes a nutritionally significant amount of omega-3 fatty acid, when the actual amount of SDA may be negligible (for example, when SDA soybean oil is used as a minor ingredient in food).

In addition, consumers could assume inappropriately that SDA provides an equivalent amount of long chain omega-3 fatty acids derived from fish. On balance, FSANZ concluded that an additional labelling statement would not be appropriate in this case. The general labelling requirements for GM foods, in addition to the permitted voluntary use of a PUFA claim, will provide consumers with adequate information to enable an informed choice.

Further, it should be noted that all soybean oil, whether GM or non-GM, is required to carry a mandatory allergen declaration, due to the possible presence of naturally occurring soybean allergens. Conditions for use of specific fats and oils are specified further in the Table to clause 4 of Standard 1.2.4 – Labelling of Ingredients. In particular, where the source of vegetable oil is peanuts, soybean or sesame, the specific source must be declared. Consequently, oil derived from MON87769 will always need to be identified as ‘soybean oil’, rather than the generic ‘vegetable oil’ as may be the case for some other oils.

7. Detection method

The Implementation Sub-Committee (ISC), a sub-committee of the 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, who would identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM applications. As part of its remit, the EAG will make recommendations to Australian and New Zealand enforcement agencies on suitable methods of analysis.

Under existing FSANZ requirements, the Applicant is required to confirm that there is detection methodology for this GM food. Standard PCR protocols are commercially available to detect regulatory elements that are common to many GM foods; these may be used routinely for foods as an initial screen for the presence of GM DNA. For event-specific detection, the complete nucleotide sequence of the inserted DNA and junction regions in MON87769 soybean has been supplied by the Applicant. This information enables the use of standard PCR protocols to detect novel DNA characteristic of MON87769 soybean using event-specific oligonucleotide primers. In some laboratories with established expertise in GM food detection, it may be appropriate to use existing PCR primers, which could reduce analytical costs.

In this case, soybean oil derived from MON87769 could also be uniquely identified by the presence of SDA. Standard fatty acid analysis would therefore be suitable as a method for detecting the presence of this soybean oil in certain foods.

8. Options

There were no non-regulatory options for this Application. The two regulatory options considered for this Application were:

8.1 Option 1 – reject the draft variation

Reject the draft variation to the Code to list food derived from SDA soybean line MON87769 in the Schedule to the Standard, thus maintaining the *status quo*.

8.2 Option 2 – approve the draft variation

Approve the draft variation to Standard 1.5.2 to permit the sale and use of food derived from SDA soybean line MON87769 in the Schedule.

9. Impact Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required under s 29 of the FSANZ Act to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the potential costs and benefits of the regulation, and its health, economic and social impacts. This section is not intended to be an exhaustive, quantitative dollar analysis of the options. Rather, it seeks to highlight the qualitative impacts of criteria that are relevant to each option. The criteria are deliberately limited to broad areas such as consumer information, compliance and trade.

In November 2010, the Office of Best Practice Regulation (OBPR) issued certain exemptions from the need for FSANZ to inform that agency about a number of Standards matters because of their routine nature (in a letter to FSANZ dated 24 November 2010 (reference 12065)). The exemption includes GM food applications submitted to FSANZ. It is therefore appropriate for FSANZ to consider any likely impacts based on generally available information.

9.1 Affected Parties

The affected parties may include the following:

- Consumers, 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
 - food retailers.
- Government:
 - enforcement agencies
 - national Governments, in terms of trade and World Trade Organization (WTO) obligations.

MON87769 soybean has been developed for limited agricultural production overseas in North America and will be channelled through an identity preserved (IP) management and distribution system. The Applicant does not appear to have 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. This is independently assessed by the Office of the Gene Technology Regulator (OGTR) in Australia, and by the Environmental Risk Management Authority (ERMA) in New Zealand before commercial release in either country could be permitted.

9.2 Benefit Cost Analysis

9.2.1 Option 1 – reject the draft variation to Standard 1.5.2

Consumers: Possible restriction of some imported food products if they contained soybean oil or other derivatives of soybean, for example lecithin or protein isolate, derived from soybean line MON87769.

No impact on consumers wishing to avoid GM foods, as food from MON87769 soybean is not currently permitted in the food supply.

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

Industry: Possible restriction on imports of soybean food products once MON87769 soybean is commercialised overseas.

Potential longer-term impact – any successful WTO challenge has the potential to impact adversely on the food industry.

9.2.2 Option 2 – approve the draft variation to Standard 1.5.2

Consumers: No restriction on imported foods containing MON87769 soybean.

The use of SDA soybean oil as a replacement for more expensive omega-3 containing-oils, could result in savings that may be passed on to consumers as cheaper food prices for certain products.

Mandatory labelling of SDA soybean oil and other derivatives of MON87769 soybean would allow consumers wishing to avoid GM foods to do so.

Government: Benefit in that any imported foods containing MON87769 soybean would be compliant with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of MON87769 soybean would ensure no conflict with WTO responsibilities.

Possible impact on monitoring resources, as all foods derived from MON87769 soybean would need to be labelled as 'genetically modified'.

Industry: Importers of processed foods containing soybean derivatives would benefit as foods derived from MON87769 soybean would be compliant with the Code, allowing broader market access.

Increased choice in raw materials for use in foods manufactured using specific soybean derivatives.

Retailers may be able to offer a broader range of foods, including imported foods.

Possible cost to food industry to comply with mandatory labelling requirements for foods derived from MON87769 soybean.

9.3 Comparison of Options

One possible impact of Option 1 could be to deny consumers broader access to foods containing omega-3 fatty acids at potentially cheaper prices than is currently possible with conventional sources such as fish oil. As food from SDA soybean line MON87769 has been found to be as safe as food from conventional varieties of soybean, Option 1 was 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 MON87769 soybean by other countries could limit the availability of certain imported foods in the Australian and New Zealand markets.

Based on the conclusions of the safety and nutrition assessments, the potential benefits of Option 2 outweighed the potential costs. Approval of the draft variation to Standard 1.5.2 permitting food derived from SDA soybean line MON87769 is therefore the preferred option.

COMMUNICATION AND CONSULTATION STRATEGY

10. Communication

This Application was considered a routine matter and therefore FSANZ applied a basic communication strategy. All reports prepared in the assessment of this Application were distributed to major stakeholders and posted on the FSANZ website. Email alerts were issued to subscribers to the Circular and other interested parties. FSANZ also issued a media release to draw journalists' attention to this Application. Individuals and organisations that made submissions on this Application and the Applicant were notified at each stage of the assessment.

The FSANZ Board's decision to approve the variation to the Code has been notified to the Ministerial Council. If the Ministerial Council does not request a review of the decision, 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.

11. Consultation

11.1 Public consultation

As this Application was assessed under the Major Procedure, there were two rounds of public consultation. The 1st Assessment Report was open for public consultation for a period of nine weeks, between 23 November 2010 and 25 January 2011. Comments were specifically sought on the scientific aspects of this Application, in particular, information relevant to the Safety and Nutrition Assessments of food derived from SDA soybean line MON87769. Nine submissions were received. Minor modifications were made to these reports to address the need for clarification or additional information where necessary. The amended assessments were released with the 2nd Assessment Report.

The 2nd Assessment Report, which included a proposed draft variation to the Code, was open for comment between 7 April and 5 May 2011. Six submissions were received. A summary of these submissions is at **Attachment 2** to this Report. Responses to the main issues raised in submissions are provided below.

11.2 General issues

A number of general issues relating to GM foods have been addressed in previous assessments and specific information is available from the FSANZ website³.

In relation to GM foods, novel foods, or substances added to foods requiring a comprehensive pre-market assessment, a scientific, evidence-based assessment is used to establish that the food or substance is safe for human consumption.

³ <http://www.foodstandards.gov.au/foodmatters/gmfoods/frequentlyaskedquest3862.cfm>

For GM foods, this requires evidence to show that the proposed food is as safe as the existing counterpart food, on a case-by-case basis. FSANZ will not approve a GM food if any public health and safety concerns have been identified in the assessment.

11.3 Specific issues

Several submitters identified a number of minor typographical errors and omissions in the Supporting Documents, and appropriate corrections have been completed. The revised SD2 and SD1 underpin the decision on the draft variation to the Code, outlined in this Approval Report.

The following issues specific to the assessment of SDA soybean line MON87769 were raised in submissions and are addressed below.

11.3.1 SDA soybean oil as a source of omega-3 fatty acids

Noting that 3.7 g/day of SDA is required to show a statistically significant response in EPA levels in erythrocytes, South Australia Health (SA Health) considered that FSANZ had possibly overstated the potential benefits of SDA soybean oil as a source of omega-3 fatty acids. Given that the National Heart Foundation has found that a diet with 2 g/day ALA decreases the risk of heart disease, SA Health considers that this suggests a higher intake of SDA would be required, whilst noting that intakes of soybean oil in Australia are normally low.

11.3.1.1 Response

FSANZ has defined the scope of this assessment in the 1st and 2nd Assessment Reports. The primary purpose of undertaking a pre-market assessment of a GM food is to determine whether it is as safe as its conventional counterpart food, if approved for human consumption. Due to the nutrient change in MON87769 soybean, FSANZ considered that a nutrition assessment (SD2) was warranted to ensure that using SDA soybean oil in foods would not result in any adverse impact on the diet.

The assessment did not aim to evaluate any potential health benefits from incorporating SDA soybean oil into foods. However, as the applicant had identified SDA soybean oil as an alternate source of omega-3 PUFAs, FSANZ included in its nutrition assessment a comparison of the physiological effects of SDA soybean oil with other sources of omega-3 PUFAs. The evidence presented in SD2 indicates that SDA is more effective in achieving an increase in erythrocyte EPA levels than ALA-rich foods such as canola oil, but less effective than EPA-rich foods such as seafood. Consequently, while the more efficient conversion of SDA to EPA could lead to the assumption that SDA would have similar disease outcomes to ALA, this issue has not been explicitly addressed in this assessment.

As for other edible oils, FSANZ considers that the decision to use SDA soybean oil in specific products will be taken by individual food manufacturers according to their commercial requirements and intended uses, which could include altering the fatty acid profile of certain foods.

11.3.2 Commercial plant-based sources of long chain omega-3 fatty acids

FSANZ stated in its assessment that there are no commercially available plant sources of long chain omega-3 fatty acids. SA Health claims that FSANZ has overlooked canola oil, with approximately 10% of its total fatty acids being of the omega-3 type.

11.3.2.1 Response

According to NUTTAB 2010, the fatty acid composition of canola oil comprises primarily monounsaturated fatty acids (62%) and short-chain polyunsaturated fatty acids (30%). As ALA (C18:3) is typically considered to be a short-chain PUFA, there are no long chain fatty acids in canola oil.

11.3.3 Ratio of omega-6 to omega-3 fatty acids in the diet

The consumer group M.A.D.G.E. questions the findings that SDA is converted to EPA at the efficiency rates described in the assessment, and questions whether there is any conversion at all. The ratio of omega-6:omega-3 fatty acids in the diet is said to be a more significant determinant of EPA levels, and it is claimed that this has been overlooked in the FSANZ assessment.

11.3.3.1 Response

The ratio of omega-6 to omega-3 PUFAs in SDA soybean oil is much lower than occurs in conventional soybean oil (<1 compared with 8, see Table 1 below). The nutrition assessment found that conversion of short-chain omega-3 PUFAs to long chain omega-3 PUFAs depends on a number of individual and concurrent dietary factors, and notes, in particular, that the ratio of omega-6 to omega-3 PUFAs in the whole diet is one of these contributing factors.

In the studies included in the nutrition assessment, this factor was addressed by generally excluding study participants if they regularly consumed foods rich in omega-3 PUFAs. Although none of the studies rigorously controlled for diet, most study protocols required participants to maintain their usual dietary patterns and in some cases record their food consumption. Where this was done, there were no significant differences in macronutrient or energy intake between the treatment groups (James *et al.* 2003; Lemke *et al.* 2010). Thus, the increase in EPA blood levels with SDA oil compared with conventional soybean oil is likely to be due to the higher SDA content.

Table 1: Linoleic acid (LA) and α -linolenic acid (ALA) fatty acid content (% total fatty acids) and ratio of omega-6:omega-3 PUFAs in a number of commercially available edible oils

Source of oil	Omega-6 PUFA	Omega-3 PUFA	Ratio of omega-6:omega-3 PUFAs
Safflower	75.6	0.3	76
Grapeseed	66.7	0.3	67
Sunflower	62.2	0.3	62
Peanut	34.8	0.3	35
Almond	25.4	0	25
Olive	8.6	0.5	9
Soybean	57.7	7.5	8
Canola	20.3	9.5	2
SDA soybean oil	29.9	37.3	<1

Source: NUTTAB 2010, except for SDA soybean oil where the values were obtained from Application A1041.

Some nutritionists argue that the ratio of omega-6 to omega-3 fatty acids has become unbalanced in the modern Western diet, largely because of greatly increased intakes of LA, an omega-6 PUFA, from foods such as polyunsaturated margarines and oils (Stanton, 1997).

In small quantities, LA is an important dietary component because it is converted in the body to an essential omega-6 fatty acid, arachidonic acid (C20:4) which in turn leads to the synthesis of physiologically active compounds such as prostaglandins and thromboxanes.

As the Table above shows, omega-3 PUFAs (ALA, SDA, EPA and DHA) are more limited in the food supply. The main dietary sources of the essential long-chain omega-3 PUFAs (EPA and DHA) are limited to fish and marine oils. Dietary sources of the short-chain omega-3 PUFAs are predominantly vegetables and some seeds, canola and soybean oils (mostly conventional varieties). SDA-rich soybean oil simply represents an alternative source of omega-3 PUFAs, albeit one in which the predominant fatty acid, SDA, is one metabolic step closer to the long-chain omega-3 PUFAs than its precursor, ALA.

The enzymatic conversion of ALA to SDA by $\Delta 6$ -desaturase, and then of SDA ultimately to the long-chain omega-3 PUFAs is well-known and widely documented. Some nutritionists consider that, for those who do not eat fish and therefore rely on making the essential EPA and DHA from ALA, an excess of LA in the diet is unfavourable (Stanton, 1997). This is because both LA and ALA are competing substrates for the $\Delta 6$ -desaturase enzyme, and an excess of LA will bias the formation of intermediates in the omega-6 pathway, at the expense of omega-3 intermediates.

Whilst there is wide public interest in reducing consumption of saturated fats in favour of polyunsaturates, consumers in general are unlikely to choose foods in order to manipulate the ratio of omega-6 to omega-3 fatty acids in their diet. Consequently, although the balance of omega-6 and omega-3 fatty acids in the diet to some extent affects the biosynthesis of EPA, this is not a major consideration in the assessment of MON87769 soybean. The results of the clinical trials conducted by James *et al.* 2003 and Lemke *et al.* 2010 therefore remain relevant to the nutrition and safety assessments of SDA soybean.

11.3.4 *Trans fatty acids*

M.A.D.G.E. asserts that the TFA content of SDA soybean oil was not adequately considered in the clinical trials, given that TFAs are reported to be a factor affecting the incidence of high triglycerides. It was noted that the results of the rat feeding study with SDA soybean meal show that the highest triglyceride levels were measured in animals in the highest test group, that is, those receiving 15% SDA soybean meal.

11.3.4.1 Response

FSANZ's nutrition assessment noted that the TFA content of SDA soybean oil is within the TFA range of commercially available cooking oils. As such, FSANZ considers that there is no need to specifically assess TFA outcomes in clinical studies in response to consumption of SDA soybean oil. Overall, FSANZ considers that the introduction of SDA soybean oil to the food supply would have negligible impact on the levels of dietary TFA.

11.3.5 *Digestibility of the novel proteins*

M.A.D.G.E. reiterated a concern with FSANZ's approach to assessing the digestibility of the novel proteins in SDA soybean ($\Delta 6$ - and $\Delta 15$ -desaturases). A recent paper (Aris and Leblanc, 2011), which reported the detection of the Cry1Ab insecticidal protein in the blood of pregnant women and their new-born infants, was cited as evidence that existing methods of assessment of GM proteins are inadequate.

11.3.5.1 Response

The paper by Aris and Leblanc is not directly relevant to the assessment of MON87769 soybean. FSANZ has evaluated the results and conclusions of this study linking Cry1Ab protein in blood to GM foods, as part of our normal monitoring procedures. In the interests of informed and balanced debate, FSANZ has posted its scientific opinion of the study (Aris and Leblanc, 2011) on the website at:

<http://www.foodstandards.gov.au/consumerinformation/gmfoods/fsanzresponsetostudy5185.cfm>.

There is scientific consensus on the types of data that best support an assessment of potential toxicity and allergenicity in humans. A weight-of-evidence approach is widely adopted by food regulatory agencies, because there is no one definitive scientific method that will, for example, predict whether a protein is likely to act as a food allergen. The Applicant is required to conduct studies on the novel protein to test a number of its properties considered relevant for this part of the safety assessment. This includes a bioinformatic analysis as well as a number of biochemical and physicochemical tests that have been appropriately validated for this purpose. In this regard, FSANZ's data requirements are entirely consistent with the safety assessment approach of similar regulatory agencies and international guidelines such as those of the Codex Alimentarius Commission⁴.

11.3.6 Labelling

The Ministry of Agriculture and Forestry (MAF), incorporating the former New Zealand Food Safety Authority, considers that FSANZ should explicitly state which labelling statements would be permitted on SDA soybean oil under current labelling provisions in the Code.

11.6.3.1 Response

As discussed in section 6 of the 2nd Assessment Report, food derived from SDA soybean MON87769, if approved, would be required to carry the mandatory statement 'genetically modified' in conjunction with the name of the food or ingredient in accordance with labelling provisions in Standard 1.5.2.

In addition, a voluntary polyunsaturated fatty acid claim may be made on SDA soybean oil when the conditions in clause 12 of Standard 1.2.8 are met. Subclause 5(7) of this Standard prescribes how a voluntary polyunsaturated fatty acid claim must be declared in the nutrition information panel. For example, 'stearidonic acid' may be listed as a sub-sub-group nutrient that is indented under the 'polyunsaturated' sub-group nutrient. The 'polyunsaturated' sub-group nutrient would then be indented under 'total fat'. Subclause 12(2) of Standard 1.2.8 provides for the quantity of fatty acids to be set out in the nutrition information panel as a minimum or maximum quantity in a serving of the food. Any voluntary polyunsaturated fatty acid claim would also trigger the requirement to declare *trans* fatty acids and monounsaturated fatty acids in the nutrition information panel (subclause 5(4)).

Clause 4 of Standard 1.2.4 states that ingredients must be declared in the statement of ingredients using:

- the common name of the ingredient, or
- a name or a name that describes the true nature of the ingredient, or
- where applicable, a generic name set out in the Table to clause 4.

⁴ Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Foods Derived From Biotechnology (2004).

The Table to clause 4 states that where the source of vegetable oil is peanut, soybean or sesame the specific source name must be declared in the statement of ingredients.

11.3.7 *Detection methodology*

Queensland Health requested FSANZ to provide the detection methodology for this GM food to Queensland Health Forensic and Scientific Services.

11.3.7.1 Response

In Section 7, FSANZ has outlined the information readily available to allow testing of foods for the presence of SDA soybean MON87769. FSANZ contacted the Queensland Health Forensic and Scientific Services laboratories directly to determine the information that would be required for GM testing purposes. FSANZ was informed that the laboratories have well-developed capability for extracting DNA from foods and for conducting PCR analyses. Therefore, provision of the nucleotide sequence specific to the insert in MON87769 would be sufficient for event-specific detection of this food.

11.4 World Trade Organization

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

The inclusion of food derived from MON87769 soybean in the Code would have a trade enabling effect as it would permit any foods containing this variety of soybean to be imported into Australia and New Zealand and sold, where currently they would be prohibited. As a result, WTO notification of the proposed draft variation to the Code was not necessary for this Application.

CONCLUSION

12. Conclusion and Decision

Decision

To approve the variation to Standard 1.5.2 – Food produced using Gene Technology, to include food derived from soybean line MON87769 producing stearidonic acid, in the Schedule.

12.1 Reasons for Decision

On the basis of the available scientific evidence, a variation to the Code giving approval to the sale and use of food derived from SDA soybean line MON87769 in Australia and New Zealand is proposed for the following reasons:

- the safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce SDA soybean MON87769
- food derived from SDA soybean MON87769 is equivalent to commercially available soybean varieties in terms of its safety for human consumption and nutritional adequacy

- labelling will be required for all foods derived from SDA soybean MON87769 due to the altered nutrient profile
- a regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is a variation to the Code, and
- there are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same end.

13. Implementation and Review

Subject to a request from the Ministerial Council for a review of FSANZ's decision, the proposed variation to the Code is expected to come into effect on gazettal.

REFERENCES

Aris A and Leblanc S (2011). Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada. *Reprod Toxicol* 31(4): 528-533.

FSANZ (2007). Safety Assessment of Genetically Modified Foods – Guidance Document http://www.foodstandards.gov.au/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf

Harris WS, Sands SA, Windsor SL, Hakim AA, Stevens TL (2004) Omega-3 fatty acids in cardiac biopsies from heart transplantation patients. *Circulation*, 110: 1645-1649.

Stanton, R. (1997). Good fats, bad fats. Allen & Unwin, Australia. ISBN 1864483180.

ATTACHMENTS

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

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



**Food Standards (Application A1041 – Food derived from SDA Soybean Line MON87769)
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 A1041 – Food derived from SDA Soybean Line MON 87769) Variation*.

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

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

3 Commencement

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

SCHEDULE

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

	7.x	Food derived from soybean line MON87769 producing stearidonic acid	
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Summary of Public Submissions on 2nd Assessment Report

Submitter	Comments
<p>Hugh Halliday (NZ)</p>	<ul style="list-style-type: none"> ▪ Considers FSANZ only pretends to regulate GM products. [There is] political pressure from the USA government on the NZ government. ▪ Scientists working in government do not take into account the fact that the land is being ruined, Monsanto has a mission to control all food and water supplies, [there is] evidence of harm to animals and therefore to humans, farmers are sued by Monsanto and put out of business. ▪ States that GM products are the biggest mistake the world has made.
<p>Food Policy and Programs Branch, South Australia Health</p>	<ul style="list-style-type: none"> ▪ Supports approval of the Application. States that an increase in the supply of GM foods will increase enforcement costs which should be considered in the cost benefit analysis. ▪ The report may overstate the significance and usefulness of SDA to omega-3 intakes. Although there is evidence that the conversion of SDA to EPA is several times more efficient than the conversion of ALA to EPA, ALA is still considered a source of omega-3 PUFAs. A number of plant-based foods already supply ALA in the diet, including conventional soybean oil. Furthermore, there was no measured effect of SDA on DHA levels. ▪ Canola oil is a commercially available plant based source of long chain omega-3 PUFA, with approximately 10% of total fatty acids being omega-3. ▪ Given the Nutrient Reference values for ALA for men (1.3 g/day) and women (0.8 g/day), and the Heart Foundation's findings that a diet with 2 g/day of ALA decreases the risk of heart disease, the intake of 3.7 g/day of SDA to achieve a statistically significant increase in EPA in blood requires further discussion. ▪ Supports the labelling requirement for SDA soybean oil. Consideration should be given to alerting consumers to the altered nutrient profile. It is noted however that this has not been required in the past for other nutrient-altered oils. ▪ Agrees that a voluntary PUFA claim is valid. ▪ Further guidance in the Code regarding labelling of GM foods with altered characteristics would be appropriate due to the increasing numbers of products in this category.
<p>Ministry of Agriculture and Forestry (formerly New Zealand Food Safety Authority)</p>	<ul style="list-style-type: none"> ▪ Agrees with the conclusions of the nutrition assessment and considers SDA soybean oil is as safe as oil derived from conventional soybean. ▪ In the nutrition assessment, the paper by Burdge should be dated as published in 2006, not 2010. ▪ Two published papers by Burdge and a textbook on human nutrition (Essentials of Human Nutrition; Eds J. Mann and A.S. Truswell, Second ed. Oxford University Press; 2002) support the role of $\Delta 6$-desaturase in the conversion of DPA to DHA in humans. ▪ Considers that consuming more of either SDA or EPA will not lead necessarily to increased levels of DHA. The omega-3 index is improved by the increase in EPA tissue concentrations.

Submitter	Comments
	<ul style="list-style-type: none"> ▪ Agrees with FSANZ that SDA soybean oil can only be described as 'genetically modified', as any reference to SDA would constitute an omega-3 claim, which is not currently permitted. ▪ MAF supports the FSANZ view that a mandatory declaration for SDA content may imply that the food contributes a nutritionally significant amount of omega-3 fatty acids, which could be misleading for consumers. However, the discussion on possible voluntary permissions should be clarified in the Approval Report.
<p>Mothers Are Demystifying Genetic Engineering (M.A.D.G.E.)</p>	<ul style="list-style-type: none"> ▪ Opposed to the Application for a variety of reasons. ▪ Refers to the fact that the Applicant has taken out a forward-looking patent on this crop, which has the capacity to capture both income and food in the marketplace. Considers the patents generate bias in the science underpinning the application. Considers that FSANZ did not discuss or evaluate the quality and reliability of the data considering possible bias. ▪ Considers that, because this was a paid application, FSANZ also has a funding bias. ▪ Considers that personal biases at FSANZ are also well-documented and could include: past work history, economic, religious and political beliefs, academic or career prospects, personal financial responsibilities and the need to maintain steady employment, the values placed on other people's children, how parenting should be conducted, and views on the risks one should carry through life. States that personal bias could be significant because it may be that only one person at FSANZ thoroughly reads the application on behalf of a population of 22 million people. ▪ Considers that the safety and nutrition assessments were not thoroughly conducted, nor properly referenced. ▪ Questions accessibility to a reference (Heart Foundation, 2008) cited in the nutrition assessment, and refers to this as a pseudo-reference. ▪ Notes several errors in Tables A1 and 2 of the nutrition assessment. ▪ Reiterates that not all of the studies submitted by the Applicant for assessment were conducted according to GLP, and those should not have been accepted. Asserts that accepting non-GLP studies contravenes FSANZ's own stated requirements on data quality. ▪ Re-states that the assessment should be repeated to show compliance with recommendations made by the Auditor General. ▪ Challenges the findings that SDA converts to EPA at the efficiency rates stated, if at all. Considers the O6:O3 ratio in the diet highly relevant and this was not properly considered in the clinical studies with SDA. States that there is a genetic, possibly epigenetic, likely hormonally affected mechanism for LC-PUFA conversion about which we do not seem to have a lot of understanding. ▪ Notes that there was no report of conversion [of SDA] to DHA, the fatty acid with the predominant reputation for health benefit. States that females appear to more readily produce this fatty acid compared with males, which suggests a hormonal mechanism but it seems to be a mystery in general.

Submitter	Comments
	<ul style="list-style-type: none"> ▪ States that SDA could turn out to be little more than a gimmick. Notes that SDA is not part of our regular diet and over the millenniums of human existence, a plant has not been bred for the sole purpose of consuming SDA. Asks the question: Is it possible that it is an irrelevant and perhaps un-utilised fatty acid in the human diet? ▪ Questions whether FSANZ considers it strange that Monsanto went to the trouble of testing GM SDA soy oil in rats, tested SDA soy meal in rats and chickens, yet did not measure any variables related to the O3 feature of the product. Asks whether it would be appropriate to cut up a sacrificed rat's heart/brain to see if there is some additional DHA deposition around the heart? Notes this was not done. In addition, when the testing bodies report that they did not comply with GLP, how can we know what material was actually tested? How does FSANZ account for the potential for misconduct, and has FSANZ ever requested material meant to be archived as a GLP requirement to verify the claims made by the Applicant? ▪ In the SDA soy meal study in rats, it might be worth FSANZ re-considering the apparent increase in triglyceride levels in the highest SDA test group. ▪ In the human study by Lemke, the tests do not provide sufficient evidence for a null effect on triglyceride levels from the <i>trans</i> fatty acids in the oil, or from some other effect related to the genetic modification. An appropriate study should be done to see if people with high triglycerides could be affected by this product. ▪ In any case, considers that the results of the Lemke study are inconclusive because of the number of subjects who dropped out of the study, particularly noted to be in the GM SDA group. ▪ Considers that there is no justification for a health claim for this product. There were no beneficial findings relating to cholesterol, LDL, HDL or TG. ▪ Concerning the safety assessment, FSANZ did not respond to the call for each of the protein products that were recognised by the specific antibodies to be identified and tested. ▪ Suggests FSANZ give consideration to the work on GM plant vaccines. FSANZ claimed that vaccines research has no relevance to food, yet edible vaccines are likely in the future. ▪ Claims that the assessment did not present a discussion of potential allergenicity of all protein bands detected on Western blots. ▪ Calls for FSANZ to undertake further investigative work into the risks of the patented CpG oligonucleotide acting as an immunostimulant. ▪ States that, on Monsanto's recommendation, FSANZ has merely assumed digestion of GM proteins, and is clearly wrong. Cites the Aris and Leblanc paper as evidence that the Cry1Ab protein is detected in pregnant women just before they gave birth and in the blood of their newly born infants.
Queensland Health (whole of Queensland Government response)	<ul style="list-style-type: none"> ▪ Requests advice on the progress of this application to regulatory agencies in other countries (seeking food and/or feed approval). ▪ States that the advice provided by FSANZ to the Office of Best Practice Regulation (OBPR) in relation to this Application, was not provided in the 2nd Assessment Report, as requested by Queensland Health in their first round submission.

Submitter	Comments
	<ul style="list-style-type: none"> ▪ Requests FSANZ to provide the detection method to Queensland Health Forensic & Scientific Services, to determine whether it will be possible for the Standard to be appropriately enforced.
The Food Technology Association of Australia	<ul style="list-style-type: none"> ▪ Supports Option 2, approval of the Application. ▪ Supports labelling of the product due to the altered nutrient profile.