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

7 April 2011
[7-11]

APPLICATION A1041
FOOD DERIVED FROM SDA SOYBEAN LINE MON87769
2nd ASSESSMENT 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 claims 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 the USA 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.**
- **Several technical issues raised in submissions have been addressed in this report.**
- **FSANZ has prepared a draft variation to Standard 1.5.2 Food produced using Gene Technology for public comment.**
- **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 new 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 acids, eicosapentenaenoic acid (EPA) and docosahexaenoic acid (DHA). SDA, which is normally present in only a few foods, is one of the metabolic intermediates in this pathway between ALA and EPA. However, as SDA is one reaction step closer to the production of long-chain EPA, the rate limiting conversion of ALA to SDA is overcome.

Fish and marine oils are typically the most significant dietary sources of EPA and DHA, however these products are susceptible to oxidation and prone to undesirable odours and taste. The Applicant claims that 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 therefore be used similarly.

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 is being assessed as a 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 s 18 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), is the protection of public health and safety. Accordingly, the safety assessment forms the central component in considering this Application. FSANZ has considered all submissions received in the first consultation period and has addressed issues, particularly those relevant to the safety of food derived from MON 87769 soybean. Where necessary, additional or amended information has been incorporated into this 2nd Assessment Report and Supporting Documents.

Safety Assessment

FSANZ has 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 reference material, food derived from SDA soybean line MON87769 is considered as safe and nutritious as food derived from other commercial 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 indicate that dietary SDA (3.7 g/day in supplement form) results in significant increases in EPA levels in blood plasma and erythrocytes, compared with a placebo group, but had no effect on DHA levels.

The level of *trans* fatty acids in SDA soybean oil is higher than in conventional soybean oil, however the difference is small and the levels are comparable to other commonly consumed vegetable oils.

Overall, the introduction of MON 87769 soybean into the food supply is not expected to have any 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 *Food Standards Australia New Zealand Act 1991* (FSANZ Act); that is, the provision of adequate information relating to food to enable consumers to make informed choices.

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 introduced changes in the fatty acid composition of the oil.

FSANZ considers that the general labelling requirements for GM foods, in addition to allowing for voluntary claims relating to polyunsaturated fatty acid content, would provide consumers with adequate information on this product to enable an informed choice.

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) concludes 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 *Food Standards Australia New Zealand Act 1991* (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.

Preferred Approach

Prepare a draft variation to Standard 1.5.2 – Food produced using Gene Technology to include food derived from soybean line MON87769 in the Schedule.

Reasons for Preferred Approach

On the basis of the available scientific evidence, a draft variation to the Code has been prepared giving approval to the sale and use of food derived from SDA soybean line MON87769 in Australia and New Zealand, 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 MON87769 soybean is as safe and nutritious as food from the conventional counterpart and other commercially available soybean varieties
- mandatory 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 Option 2, to prepare a 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.

Consultation

Consultation on the 1st Assessment was conducted over a period of nine weeks, and nine submissions were received (summarised in **Attachment 2**). Public submissions are now invited on this 2nd Assessment Report, which includes a draft variation to Standard 1.5.2. Comments received in the second consultation will be used to assist in preparing the Approval Report, to complete the assessment of this Application.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variation to the Code based on regulation impact principles for the purpose of preparing a variation to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

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

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Changing the Code tab and then through Documents for Public Comment.

Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 5 May 2011

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

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

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

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

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

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

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SUPPORTING DOCUMENTS

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1041food4746.cfm

SD1: Safety Assessment Report (2nd Assessment)
SD2: Nutrition Assessment Report (2nd Assessment)

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) 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), eicosapentenaenoic 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 fish oils 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 undesirable (rancid) odours and taste. 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.

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. Minor amendments to the Nutrition Assessment (**Supporting Document 2**) have been made in response to comments received in the first consultation period. Public comment is now sought on this 2nd Assessment Report, which includes the draft variation to Standard 1.5.2, prior to preparation of the Approval Report and completion of the Application.

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 broad 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 once the Ministerial Council process has been finalised.

MON87769 soybean is intended for small acreage cultivation in North America and will be identity preserved[1]. Before its release into commercial markets, the Applicant is seeking regulatory approval for MON87769 soybean in a number of trading markets, 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. The Application is being assessed as a Major Procedure.

2. Current Standard

2.1 Background

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

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives, which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

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

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

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

- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Questions for first assessment

In completing the 1st Assessment of this Application, the following questions were addressed:

Based on information provided by the Applicant on the nature of the genetic modification, the molecular characterisation, the characterisation of the novel proteins, the compositional analysis and consideration of the nutritional issues, is food derived from SDA soybean line MON87769 as safe for human consumption as food derived from conventional varieties of soybean?

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?

Are there any other considerations that would influence the outcome of this assessment?

RISK ASSESSMENT

Food derived from SDA soybean line MON87769 has been evaluated according to the safety assessment guidelines prepared by FSANZ (**Supporting Document 1**), and in a separate nutrition assessment (**Supporting Document 2**). The summary and conclusions from these assessments are presented below. In addition to information supplied by the Applicant, other available resource materials including published scientific literature and general technical information were 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.

This assessment was confined to food safety and nutritional issues, and excluded consideration of any implied nutritional benefits arising from the consumption of long-chain omega-3 fatty acids. Any risks related to the release into the environment of GM plants used in food production, the safety of animal feed, or animals consuming feed derived from GM plants, or the safety of food derived from the non-GM (conventional) plant have not been addressed in this assessment.

5.2 Outcomes of the Safety Assessment

MON87769 soybean contains two novel genes, *Pj.D6D* and *Nc.fad3*. These encode respectively a delta-6 desaturase from the plant species *Primula juliae*, and a delta-15 desaturase from *Neurospora 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. Delta-6 desaturase 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 the delta-15 desaturase, *Neurospora 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 seeds. The mean concentration of Pj.Δ6D and Nc.Δ15D in harvested soybean seed is 1.8 and 10.0 µg/g dry weight, respectively. The proteins conform in size and amino acid sequence to that expected, are immunoreactive to the corresponding antibodies, are not glycosylated, and exhibit the expected functional 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 acute oral toxicity studies on Pj.Δ6D and Nc.Δ15D in mice confirmed the absence of 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 that from 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 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 nutrition assessment addressed the nutritional implications of the genetic modification that results in the production of SDA in the seeds of MON 87769 soybean plants, and the consequential increase in the *trans* fatty acid (TFA) content of this oil. The assessment considered a comparison between SDA-rich oils and EPA-rich oils to increase EPA in blood plasma and erythrocytes. The effect of SDA-rich and EPA-rich oils on the omega-3 index[2] was also considered.

The findings of the assessment indicated that dietary SDA at levels of 3.7 g/day or more result in significant increases in EPA in blood plasma and erythrocytes, compared with a placebo group, and that the conversion of SDA to EPA in these tissues is relatively complete. These effects were observed after eight weeks of supplementation. There was no effect of SDA on DHA levels in the blood.

The available evidence indicated that 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 higher than in conventional soybean oil, the level (0.67 g TFAs per 100 mL) is well within the range in commonly consumed edible oils (0-1.8 g TFAs per 100 mL); hence it is unlikely to increase overall TFA intakes in Australia and New Zealand above their current levels.

SDA soybean oil has the potential to be used as a source of omega-3 PUFAs, and, in so doing, indirectly contribute to the recommended increased intakes of long chain omega-3 PUFAs in the Australian and New Zealand populations. Compared with EPA-rich oil, higher levels of consumption of SDA-rich oil would be required to achieve similar tissue concentrations of EPA and DHA (as indicated by the omega-3 index).

5.4 Conclusions

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

RISK MANAGEMENT

6. Labelling

In accordance with the 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 percent 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 (the predominant food derived from SDA soybean MON87769), has the potential to be used as a source of omega-3 fatty acids. As such, SDA soybean oil may contribute to the recommended increased intakes of long chain omega-3 fatty acids in the Australian and New Zealand populations.

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 fatty acid content being made for food derived from SDA soybean MON87769. This is consistent with omega-3 claim requirements for conventional (non-GM) foods that provide a dietary source of stearidonic acid, for example, fish.

Food derived from SDA soybean MON87769 may meet the requirements for making a polyunsaturated fatty acid claim with respect to its stearidonic acid content. Subclause 12(1) of Standard 1.2.8 – Nutrition Information Requirements 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 (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 stearidonic acid, irrespective of the amount in the food.

A mandatory statement may also imply that the food contributes a nutritionally significant amount of omega-3 fatty acid, when the actual amount of stearidonic acid may be negligible (for example, when SDA soybean oil is used as a minor ingredient in food). FSANZ also notes that consumers could assume inappropriately that omega-3 stearidonic acid provides an equivalent amount of long chain omega-3 fatty acids derived from fish. On balance, FSANZ concludes that an additional labelling statement is not appropriate for food derived from SDA soybean MON87769.

FSANZ considers that the general labelling requirements for GM, in addition to voluntary claim permissions, 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 soybean line 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. Options

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

7.1 Option 1 – reject the Application

Maintain the status quo by rejecting the Application to list food derived from SDA soybean line MON87769 in the Standard.

7.2 Option 2 – prepare a draft food regulatory measure

Proceed to development of a food regulatory measure to vary Standard 1.5.2 to permit the sale and use of food derived from SDA soybean line MON87769 in the Schedule.

8. Impact Analysis

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

8.1 Affected Parties

The affected parties may include the following:

- Consumers, 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. There is no intention to apply for approval to cultivate this variety in either Australia or New Zealand.

The cultivation of any GM crop in Australia or New Zealand could have an impact on the environment. 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.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – reject Application

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.

8.2.2 Option 2 – prepare a draft variation to Standard 1.5.2

Consumers: No restriction on imported foods containing MON87769 soybean.

If SDA soybean oil was used as a replacement for more expensive omega-3 containing-oils, savings could 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.

8.3 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 other conventional sources of omega-3s. As food from SDA soybean line MON87769 has been found to be as safe as food from conventional varieties of soybean, Option 1 is likely to be inconsistent with Australia's and New Zealand's WTO obligations. Option 1 would also offer little benefit to consumers, as approval of 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 outweigh the potential costs. Preparation of a draft variation to Standard 1.5.2 giving approval to SDA soybean line MON87769 is therefore the preferred option.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

As normally applies to all GM food assessments, all reports will be available to the public on the FSANZ website and distributed to major stakeholders. The communication strategy applied to this Application involves advertising the availability of the 1st and 2nd Assessment Reports for public comment in the national press and placing the reports on the FSANZ website. In addition, FSANZ will issue a media release drawing journalists' attention to this Application. The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the assessment.

Public comments on this 2nd Assessment, which includes a draft variation to the Code, will be used in preparing the Approval Report. Following completion of an Approval Report, the draft variation will be considered for approval by the FSANZ Board.

After the FSANZ Board has considered the Approval Report, if the draft variation to the Code is approved, that decision will be notified to the Ministerial Council. If the approval of food derived from SDA soybean line MON87769 is not subject to review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the relevant changes to the Code in the national press and on the website.

10. Consultation

10.1 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, and have been summarised at **Attachment 2** to this Report. Responses to the main issues raised in submissions are provided below. Where necessary, FSANZ has addressed requests for clarification or additional information through a change to the Safety Assessment (**SD1**) or the Nutrition Assessment (**SD2**) Reports for MON87769 soybean.

As this Application is being assessed as a major procedure, there are two rounds of public comment. Submissions from the public are invited on this 2nd Assessment Report, including the proposed draft variation to the Code (**Attachment 1**).

10.2 General issues

A number of general issues were raised concerning GM foods and their assessment. The majority of general issues falling within FSANZ responsibilities have been addressed in previous assessments and specific information is available from the FSANZ website[3].

FSANZ has a statutory obligation to consider all applications on their individual merits, subject to the application meeting detailed criteria concerning format and inclusion of information. An open and transparent process of assessment is then used to develop or amend food standards as may be appropriate in Australia and New Zealand. In particular, public consultation periods are considered integral to this process, and comments received from submitters contribute to the overall effectiveness of the risk assessment.

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. 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.

10.3 Specific issues

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

10.3.1 Possible food uses of SDA soybean

Several submissions, including from the New Zealand Food Safety Authority (NZFSA), sought further information and clarification on the possible food uses of SDA soybean. The NZFSA suggested FSANZ give consideration to including a Food Technology Report in the assessment to provide further discussion on the possible effects of processing on SDA soybean oil, its stability, and whether it will be partially hydrogenated for some food applications.

[3] http://www.foodstandards.gov.au/foodmatters/gmfoods/frequentlyaskedquest3862.cfm

10.3.1.1 Response

The primary purpose of this assessment is to determine whether SDA soybean would be safe for human consumption if commercialised. As is the case with other edible oils, FSANZ considers that the decision to use SDA soybean oil in specific product formulations will be taken by food manufacturers according to individual requirements and intended uses, including altering the fatty acid profile of certain foods. In light of its nutrient profile, some of the possible food uses of SDA soybean oil are discussed below.

The composition of SDA soybean oil has similarities with blackcurrant seed and low-THC (δ-9- tetrahydrocannabinol) hempseed oil, which also contain SDA. As for all edible vegetable oils, the variable percentages of polyunsaturated and saturated fatty acids impart certain functional properties (such as melting point, smoke point, viscosity), which ultimately determine suitable food applications. As well as the type of crop, to some extent, the proportion of PUFA also varies according to where the crop is grown.

The important aspects of edible oil products are eating quality, appearance, oxidative or shelf-life stability and consistency of quality. The standard processes that produce refined, bleached and deodorised (RBD) soybean oil are to purify the oil from contaminating plant and processing materials and other impurities, and increase shelf-life. Refining of crude edible oil removes contaminants without reducing the beneficial non-glyceride components such as the tocopherols and tocotrienols, which have antioxidant activities. Bleaching reduces pigments and flavonoid compounds, oxidation products and trace metals. The final major stage in refining edible oils is deodorising, which reduces fatty acids, mono- and diglycerides, oxidation products, pigment decomposition products and pesticides. This produces commercial quality oil with decreased colour and odours, a bland flavour, and with good shelf-life stability (Gunstone *et al*).

As indicated by the Applicant, in general the range of food uses of MON 87769 soybean will be identical to the range of uses of traditional soybean products, with the only difference being that oil produced from MON 87769 soybean contains SDA. The Applicant states that the oil will be suitable for food applications in which omega-3 products are currently being used. As with other oils containing PUFAs, antioxidants may be used to maintain oxidative stability (ie. limit rancidity and fatty acid changes).

It is anticipated that SDA soybean oil would be suitable to partially replace regular soybean oil, or other oils, in a variety of food categories. A more detailed description of possible food uses suggested by the Applicant and outlined in the 1st Assessment Report, includes baked goods, breakfast cereals, grain products and pastas, sauces, salad dressings, soups and milk products such as yoghurts. In relation to possible use in margarines, it is noted that the majority of retail margarines and spreads are a blend of both liquid and solid oils.
It is possible to use modification processes, such as hydrogenation, interesterification and fractionation alone or in combination to increase the usability of purified edible oils for such products without impacting significantly on key unsaturated fatty acids. The modification processes can be used on single oils or fats, or on blends.

As well as improving stability, the conversion of unsaturated to saturated bonds via hydrogenation increases the melting point of the oil. This 'hardening' process can be stopped at any point up to complete saturation. Substantial amounts of conventional soybean oil produced in the US are partially hydrogenated to improve oxidative stability. Similarly, virtually all fish oil, which is highly unsaturated, must be hydrogenated to provide an acceptable edible product for human consumption.

10.3.2 Use of SDA soybean oil in infant formula products

NZFSA proposed that SDA soybean oil should not be used in infant formula products as a source of DHA.

10.3.2.1 Response

Fish oil and oil from certain species of marine microalgae species contain EPA and DHA, and are possible ingredient sources of long chain omega-3 fatty acids in infant formula products. However, there is no EPA or DHA in SDA soybean oil, so it cannot be considered as a source of DHA.

The applicant has given no indication that SDA soybean oil would be suitable as a source of fat in infant formula products. However, if used as the sole source of fat, it would not meet the requirement in paragraph 23(b) in Standard 2.9.1[4]. It could however be blended with other oils and used as an ingredient in infant formula products as long as the overall fatty acid composition meets the requirements in clause 23.

10.3.3 Dietary modelling

The NZFSA suggests that dietary modelling would help to ascertain the amounts of SDA soybean oil that would need to be consumed to achieve a significant increase in EPA levels in blood.

10.3.3.1 Response

FSANZ considered the following points in relation to whether dietary modelling would add value to the assessment of SDA soybean:

1. FSANZ understands from the Application that SDA soybean oil could be substituted for conventional soybean oil in a variety of food applications. The extent to which the food industry takes up the use of SDA soybean oil however is not part of this assessment.

2. Instead, the focus of this assessment is to establish that oil derived from the MON 87769 soybean line is as safe as oil derived from conventional soybean varieties already in the food supply.

3. SDA soybean oil is not considered a novel food and therefore, if found to be safe, approval will not result in restrictions or limitations on its use in foods.

4. The objective of the nutrition assessment is to demonstrate that the production of EPA is metabolically possible following intake of SDA.

5 Having established the validity of the link between dietary SDA and its conversion to EPA, there is no further need to determine that a certain level needs to be consumed each day to achieve a particular nutritional goal, nor to establish that certain amounts must be added to food/s in order to achieve this goal.

Thus, for the reasons outlined above, FSANZ considers that dietary modelling is not required, nor relevant for this assessment.

[4] Paragraph 23(b) in Standard 2.9.1 states that the fats in infant formula and follow-on formula must "have a ratio of linoleic acid to α-linolenic acid of no less than 5 to 1 and no more than 15 to 1". The ratio of these two fatty acids in SDA soybean oil is about 2:1.

However, FSANZ notes that consumption of a few teaspoons of SDA soybean oil per day would be sufficient to provide the level of SDA that has been shown to achieve the metabolic effect described above.

10.3.4 Labelling of SDA soybean oil

The NZFSA suggested that further consideration be given to whether additional labelling for SDA soybean oil would be useful to inform consumers about the nutritional change.

10.3.4.1 Response

FSANZ has considered whether or not an additional mandatory labelling statement about the nutrient change is warranted, and concludes that it is unnecessary in this case. If an additional labelling statement was mandated, it would establish an inconsistency with omega-3 claim conditions as set out in clause 13 of Standard 1.2.8. Furthermore, a mandatory statement about SDA omega-3 content could be misleading to consumers where SDA soybean oil is used as a minor ingredient in food. A reference to stearidonic acid as an omega-3 fatty acid may also mislead consumers to erroneously believe that stearidonic acid confers the same degree of health benefit as the long-chain omega-3 fatty acids derived from fish.

FSANZ reaffirms its recommendation that a voluntary polyunsaturated fatty acid claim may be made when the conditions in clause 12 of Standard 1.2.8 are met. In addition, 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.

FSANZ has informed the Applicant that currently the Code would not permit a nutrition claim on a packaged food referring to stearidonic acid as an omega-3 fatty acid. The Applicant has advised that they are not seeking permission for any such claim.

10.3.5 Trans fats in SDA soybean oil

South Australia Health suggested that consideration should be given to the impact of raised *trans* fatty acids on dietary intakes, and labelling of *trans* fats on derived foods.

10.3.5.1 Response

FSANZ does not mandate the labelling of *trans* fatty acid content of foods, unless a nutrition claim is made in respect of cholesterol or specific fatty acids. Where a nutrition claim is made about any of these substances, the amount of *trans*, polyunsaturated and monounsaturated fatty acid content must be declared in the nutrition information panel (subclause 5(4) of Standard 1.2.8). The approach proposed in the 1st Assessment Report is consistent with current labelling provisions.

The impact of TFA levels in SDA soybean in relation to dietary intakes is discussed further in the Nutrition Assessment Report (Supporting Document 2).

The conclusion is that the levels of TFA in refined SDA soybean oil are low and within the range of commercially available edible vegetable oils. Overall, FSANZ considers that the introduction of SDA soybean oil to the food supply would have negligible impact on the levels of dietary TFA.

10.3.6 Potential allergenicity

In its submission, M.A.D.G.E suggested that the safety assessment should determine whether 'chimeric sequences' are capable of immunostimulatory activity, paying particular attention to the gene originally sourced from *Neurospora crassa* in which the codon usage was altered to optimise expression in plants.

10.3.6.1 Response

Codon changes were necessary in the gene encoding the ∆15-desaturase protein to optimise expression in soybean plants. These nucleotide changes however do not alter the amino acid sequence of the protein. Optimising codon usage according to the biochemistry of the host plant is a routine step in the development of transgenic plants, depending on the source of the inserted gene.

FSANZ is aware of published research papers reporting that short bacterial plasmid DNA sequences (6 base pairs with CpG motifs) may be used as an adjuvant to stimulate immune responses in the development of vaccines. However, vaccines research has no relevance to food. As humans normally consume and digest DNA from microbes, plants, animals and even viruses in their food throughout life, dietary exposure to an infinite variety of short oligonucleotide sequences, including any given 6-mer, would occur with high frequency. Irrespective of origin, DNA is digested in the gastrointestinal tract. It is unclear how the use of DNA adjuvants in vaccine research relates to the safety assessment of a GM food.

10.3.7 Simulated digestibility tests

M.A.D.G.E. asked whether the digestibility studies on the novel proteins (∆6- and ∆15-desaturases) using SGF and SIF are relevant for infants.

10.3.7.1 Response

The safety assessment of the ∆6- and ∆15-desaturases does not rely entirely on any one analytical test. The *in vitro* digestibility studies contribute to a weight of evidence that aims to evaluate whether the novel proteins would survive digestion in the human gastrointestinal tract. The presence of intact sequences is considered to be one element that could potentially lead to an allergic response in some instances. In this case however, the *in vitro* assays with simulated intestinal fluid (SIF) indicated that both the Pj∆6D and the Nc∆15D proteins degrade rapidly when exposed to pancreatin at a neutral pH. Given the additional thermal processing that soybean meal would undergo to make it a suitable ingredient for infant formula, infants would not be expected to be exposed to the intact novel proteins. Coupled with other evidence indicating the absence of potential allergenicity, FSANZ does not consider that the novel proteins in MON 87769 soybean would pose any increased risk of allergy above levels that occur naturally with the consumption of conventional soybean proteins.

FSANZ notes that, in humans, a number of pancreatic proteolytic enzymes including trypsin, are detected in the foetus as early as three months gestation. Moreover, the published literature indicates that, in the intestinal lumen, proteolytic activity of pancreatic enzymes increases rapidly after birth in both premature and full-term infants (Hamosh, 1996). The peptides produced by pancreatic enzyme digestion are further hydrolysed by intestinal brush border peptidases. As a result, in infants, digestion of dietary protein in the intestine compensates for limited gastric proteolysis due to low acid conditions.

Most infant formula products sold in Australia are based on cows' milk, and consequently soy-based formulas comprise only a very small part of the market in Australia (less than 5% of infant formula sales). They are generally used on the basis of specific and informed dietary advice.

10.3.8 Molecular characterisation of the insertion site in MON87769

The NZFSA suggested that the safety assessment should include comment on the insertion site in the soybean genome, to confirm that it is not within a functional gene.

10.3.8.1 Response

Insertion of a transgene into an important or functional gene would have resulted in either an unviable plant or impaired agronomic traits. The plants that are selected therefore generally have insertions into non-coding regions, or into regions that, if disrupted, cause no effect on the plant's viability. In this case, the insertion in MON 87769 has not resulted in any discernible phenotypic effect, nor undesirable agronomic performance measures. The effects of the genetic modification are reflected in the intended nutrient change. For safety assessment purposes, this information is considered adequate.

10.4 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, for this Application, WTO notification of the proposed draft variation to the Code is not necessary.

CONCLUSION

11. Conclusion and Preferred Approach

Preferred Approach

Prepare a draft variation to Standard 1.5.2 – Food produced using Gene Technology to include food derived from soybean line MON87769 in the Schedule.

11.1 Reasons for Preferred Approach

On the basis of the available scientific evidence, a draft variation to the Code has been prepared giving approval to the sale and use of food derived from SDA soybean line MON87769 in Australia and New Zealand, 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 MON87769 soybean is as safe and nutritious as food from the conventional counterpart and other commercially available soybean varieties

- mandatory 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 Option 2, preparation of a draft 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.

12. Implementation and Review

Following the consultation period for this 2nd Assessment Report, an Approval Report will be completed and the draft variation to the Code will be considered for approval by the FSANZ Board. This decision will then be notified to the Ministerial Council. Following notification, the proposed draft variation to the Code is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.

REFERENCES

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

Gunstone FD, Harwood JL, Padley FB (1994) The Lipid Handbook. 2nd Edition, Chapman and Hall, London.

Hamosh M (1996) Digestion in the Newborn. Clin Perinatol. 23(2): 191-209.

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.

ATTACHMENTS

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

Attachment 1

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

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

Commencement: On gazettal

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

	7.9	Food derived from soybean line MON87769 producing stearidonic acid	

Attachment 2

Summary of Public Submissions on 1st Assessment Report

Submitter	Comments
Michelle Denise	▪ Considers that not enough independent studies have been done on the effects of new GM products on human health and the environment.
Leo Adler (NZ)	▪ Considers that GM products are associated with unknown possible risks for current and future generations of many life forms. ▪ Opposes this Application and all GM products and considers the long term impacts to be unproven.
The Food Technology Association of Australia	▪ Supports approval of the Application, however suggests that the acute oral toxicological studies should be conducted over a longer period than 2 weeks, and several subsequent and successive generations of test animals should be examined for any areas of concern.
Anna Clements	▪ Expresses concerns about the use of foreign GM materials in food. ▪ States that food can be allergenic even without proteins present, for example, anaphylaxis and peanut oil. ▪ Considers that there is insufficient information to say in what form these GM products will be presented. ▪ Comprehensive labelling of SDA soybean oil is welcome news.
Food Policy and Programs Branch, South Australia Health	▪ Supports approval of the Application. ▪ Labelling of the SDA soybean oil is important due to the modified composition. ▪ Consideration should be given to the impact of raised *trans* fatty acids on dietary intakes, and labelling of *trans* fats on derived foods.
New Zealand Food Safety Authority	▪ Agrees with the conclusions of the safety assessment that no public health and safety concerns have been identified. ▪ Suggests that the molecular characterisation should provide comment on the insertion site in the soy genome, and confirm that it is not part of a functioning gene, as raised previously in the assessment of Application A1035 (herbicide-tolerant soybean). ▪ Recommends that Figure 1 in the Nutrition Assessment (SD 2) be updated according to recent published literature outlining the enzymes involved in the omega-3 biosynthetic pathway in humans. ▪ The Executive Summary and the Nutrition Assessment should be consistent and state that consumption of SDA can lead to higher levels of EPA in body tissues, rather than higher levels of both EPA and DHA. ▪ States that EPA supplements have minimal effects on DHA levels, because the conversion of EPA to DHA is dependent on the same Δ6-desaturase that impairs conversion of ALA to SDA in humans. SDA soybean oil should therefore not be considered as a source of DHA, for example, for use in infant formula products. ▪ Suggests that dietary modelling would help to ascertain the amounts of SDA soybean oil that would need to be consumed to achieve a significant increase in EPA levels in blood.

Submitter	Comments
	▪ Suggests that the Nutrition Assessment would be enhanced by including a discussion on existing knowledge of plant sources of long chain PUFAs. ▪ Agrees with labelling of SDA soybean oil as 'genetically modified', but considers that further consideration be given to determine whether additional labelling may also be necessary to inform consumers about the nutritional change. ▪ Prescribing additional labelling of SDA soybean oil under Standard 1.5.2 to refer to omega-3 fatty acids may not be considered a nutrition claim. ▪ Agrees that a food could make a polyunsaturated fatty acid (PUFA) claim, however this would also trigger a declaration of the *trans* fatty acid content. ▪ Considers that the assessment would benefit from a food technology report, or expanded discussion of the possible food uses of SDA soybean oil, stability, and effects of processing. ▪ The possible food uses of soybean line MON 87769 should be clarified as the uses proposed in the FSANZ report differ from those stated in the application to the EU.
David Mattinson	▪ Opposes the Application and considers products by Monsanto attract worldwide criticism. ▪ Considers that there are other plant based sources of omega-3 fatty acids, such as hempseed oil, that have not been exploited and do not have unpredictable genetic risks associated with them.
Mothers Are Demystifying Genetic Engineering (M.A.D.G.E.)	▪ Opposed to the Application because of a lack of confidence in the FSANZ safety assessment process. ▪ Considers that the majority of studies submitted by the Applicant were not conducted according to GLP and therefore should not have been accepted. ▪ Considers that the assessment should be repeated to show compliance with recommendations made by the Auditor General. ▪ Claims that further discussion is needed on the chimeric sequences in this crop, particularly because of the possibility that they could exhibit immunostimulatory activity. ▪ Claims that the assessment did not present a discussion of potential allergenicity of all protein bands detected on Western blots. ▪ Requests discussion of testing done to determine the gastrointestinal safety of this food specifically in infants. ▪ Considers that, in light of alternative plant sources of omega-3 oils, including Paterson's Curse and the plant source of the gene used in MON 87769 [*Primula juliae*], the risks associated with the GM crop outweigh the benefits.
Queensland Health (whole of Queensland Government response)	▪ Requests advice on the progress of submissions by the Applicant, to regulatory agencies in other countries, seeking approval for the use of SDA soybean MON 87769 in food and/or feed. ▪ Notes that the assessment relied significantly on data submitted by the Applicant, which may not be viewed as being independent. ▪ Comments that the benefit-cost analysis is not detailed, and requests more information on advice received by FSANZ from the OBPR. ▪ Comments that a decision to approve the Application would impact on the monitoring resources of jurisdictions.