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

23 November 2010
[24-10]

APPLICATION A1041
FOOD DERIVED FROM SDA SOYBEAN LINE MON87769
1st ASSESSMENT REPORT

Executive Summary

Purpose

An Application was received from Monsanto Australia Limited on 20 January 2010, seeking an 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 is a new variety of soybean that is genetically modified (GM) to produce stearidonic acid (SDA), an omega-3 fatty acid, in the seeds of the plant. Standard 1.5.2 prohibits a food produced using gene technology from being sold or used as an ingredient or component of any food unless it is listed in that Standard. This Application is being assessed as a Major Procedure and will include two rounds of public consultation.

The novel trait in MON87769 soybean is conferred by the expression of two introduced genes encoding enzymes, delta-6 desaturase from *Primula juliae* (Pj.Δ6D) and a delta-15 desaturase from *Neurospora crassa* (Nc.Δ15D). When simultaneously expressed in the seed, SDA is produced from linoleic acid (LA) and alpha linolenic acid (ALA), both naturally present in soybean. As a result, refined oil produced from MON87769 soybean contains approximately 20–30% SDA. Conventional soybean plants lack a delta-6 desaturase gene, a minimal requirement 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 a metabolic intermediate in the omega-3 pathway. Studies have shown that consumption of SDA can lead to higher levels of EPA and DHA in body tissues, compared with ALA.

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 other commodity soybean meal and can therefore be used conventionally.

MON87769 soybean is intended for low-acreage cultivation in North America, and will be grown, transported and processed using an identity preserved system. Once commercialised, SDA soybean oil and other products could be imported into Australia and New Zealand as raw commodities, or as food ingredients. Approval in the Code is necessary before any of these products may enter the Australian and New Zealand markets.

Safety Assessment

FSANZ has completed a comprehensive safety assessment of food derived from MON87769 soybean. 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.

Nutrition Assessment

The nutrition assessment considered data from several clinical trials to determine the relative efficiency of the conversion of SDA to EPA. As with all dietary sources of SDA, conversion to EPA is variable, depending on a number of individual and concurrent dietary factors.

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. While the level of *trans* fatty acids in SDA soybean oil is higher than in the conventional form but comparable to other vegetable oils, this is unlikely to have any impact on overall intakes of *trans* fats in the Australian and New Zealand diets.

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.

Labelling

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 inherent nutritional changes. In this case, comprehensive labelling of SDA soybean oil as ‘genetically modified’ would be required because of the introduced changes in the fatty acid composition of the oil.

There is potential for consumer confusion if mandatory labelling were to address specific fatty acids such as ‘stearidonic acid’. FSANZ notes that, following public education campaigns, consumers are now more likely to have a better understanding of the terms ‘omega-3’, ‘unsaturated’ and ‘saturated’ with regard to fats, than to have an understanding of the differences between individual fatty acids. Therefore, FSANZ is proposing that the general labelling requirements for GM foods, in addition to voluntary claim permissions relating to polyunsaturated fatty acids, would provide consumers with adequate information on this product to enable an informed choice.

Labelling addresses the objective set out in paragraph 18(1)(b) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act); that is, the provision of adequate information relating to food to enable consumers to make informed choices.

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 the 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

To proceed to develop an amendment to Standard 1.5.2 – Food produced using Gene Technology to include food derived from SDA soybean line MON87769 in the Table to clause 2.

Reasons for Preferred Approach

On the basis of the available scientific evidence, proceeding to the development of an amendment to the Code to give 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 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 inherent nutritional changes

- a regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is Option 2, the development of a food regulatory measure

- there are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same end.

Consultation

Public submissions are now invited on this 1st Assessment Report. Comments are requested on the scientific aspects of this Application, in particular, information relevant to the safety assessment and nutritional impact of food derived from MON87769 soybean.

As this Application is being assessed as a major procedure, there will be two rounds of public comment. Responses to this 1st Assessment Report will be used in development of the 2nd Assessment Report for the Application.

Invitation for Submissions

FSANZ invites public comment on this Report based on regulation impact principles for the purpose of preparing an amendment 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) 18 January 2011

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

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

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

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

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

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 978 5636

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SUPPORTING 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: Application A1041 – Food Derived from SDA soybean line MON87769

SD2: Nutrition Assessment Report: Application A1041 – Food Derived from SDA Soybean line MON87769

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 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 can lead to higher levels of EPA and DHA 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 cooking, nor for use in table spreads or margarines. Soybean meal derived from MON87769 is similar in composition to other commodity soybean meal and can therefore be used in a manner similar to conventional soybean meal.

This Assessment includes a full scientific evaluation of food derived from MON87769 soybean according to FSANZ guidelines[1] to assess its safety for human consumption. Public comment is now sought on the safety assessment (**Supporting Document 1**), the nutrition assessment (**Supporting Document 2**) and proposed recommendations prior to further consideration and completion of the Application.

1. The Issue / Problem

The Applicant has developed genetically modified soybean line MON87769, which produces SDA-rich oil only in the seeds of the plant. The SDA soybean oil is intended as a plant-based alternative to the use of fish oils or other omega-3 oils in various 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 subsequently be notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

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

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[2]. 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 Table to clause 2 of 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 U.S. 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:

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

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

4. Questions for 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 and is provided in **Supporting Document 1**; a separate nutrition assessment is provided in **Supporting Document 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 restricted to food safety and nutritional issues, excluding 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 intentional change to increase the SDA content of edible soybean oil derived from MON87769 and the consequential increase in the *trans* fatty acid content of this oil.

The nutritional implications considered a comparison between the conversion of SDA-rich oils and EPA-rich oils to EPA in blood plasma and in erythrocytes. The EPA levels in these blood fractions are assumed to reflect the conversion levels of omega-3s in other human tissues. The effect of SDA-rich and EPA-rich oils on the omega-3 index[3] 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 only eight weeks of supplementation.

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 SBO, 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.

Thus, SDA soybean oil has the potential to be used as an alternate 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 an 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.

[3] 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).

RISK MANAGEMENT

6. Issues raised

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'. 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 subclause 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 subclause 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 acid. As such, SDA soybean oil may contribute to the recommended increased intakes of long chain omega-3 fatty acid intakes 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 prohibit 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.

In contrast, 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 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)].

Labelling is intended to address the objective set out in subsection 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 is considering whether the need for additional labelling requirements for nutrition information, such as an additional mandatory labelling statement to the effect that the food has been genetically modified to contain high levels of stearidonic acid, would be appropriate in this case.

FSANZ notes however, that following public education campaigns consumers are now more likely to have a better understanding of the terms 'omega-3', 'unsaturated' and 'saturated' with regard to fats, than to have an understanding of the differences between individual fatty acids. There is potential for consumer confusion if mandatory labelling addresses specific fatty acids.

Therefore, FSANZ is proposing that the general labelling requirements for GM in addition to voluntary claim permissions will provide consumers with adequate information to enable an informed choice.

7. Options

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

7.1 Option 1 – Maintain the *status quo*

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

7.2 Option 2 – Proceed to the development of a food regulatory measure

Proceed to development of a food regulatory measure to vary Standard 1.5.2 to permit the sale and use of food derived from SDA soybean line MON87769 in the Table to clause 2.

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 – maintain the status quo

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 food industry.

8.2.2 Option 2 – proceed to the development of a food regulatory measure

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 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. A variation to Standard 1.5.2 giving approval to SDA soybean line MON87769 is therefore the preferred option.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

The communication strategy applied to this Application involves advertising the availability of 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.

As normally applies to all GM food assessments, this report will be available to the public on the FSANZ website and distributed to major stakeholders. Public comments on this 1st Assessment will be used in preparing the 2nd Assessment, which will include the development of a draft variation to the Code. Following a second round of public consultation, an Approval Report will be completed and the draft variation will be considered for approval by the FSANZ Board.

The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the assessment. After the FSANZ Board has considered the Approval Report and related draft variations to the Code, if the draft variation 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

Public submissions are invited on this 1st Assessment Report. Comments are specifically sought on the scientific aspects of this Application, in particular, information relevant to the safety and nutrition assessments of food derived from SDA soybean line MON87769.

As this Application is being assessed as a major procedure, there will be two rounds of public comment. Responses to this 1st Assessment Report will be taken into consideration in developing the 2nd Assessment Report for the Application.

10.1 World Trade Organization (WTO)

As members of the 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.

This issue will be fully considered at 2nd Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

11. Conclusion and Preferred Approach

Preferred Approach

To proceed to develop an amendment to Standard 1.5.2 – Food produced using Gene Technology to include food derived from SDA soybean line MON87769 in the Table to clause 2.

11.1 Reasons for Preferred Approach

On the basis of the available scientific evidence, proceeding to the development of an amendment to the Code to give 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 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 inherent nutritional changes
- a regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is Option 2, the development of a food regulatory measure

- there are no 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 document, a 2nd Assessment Report will be prepared that includes a draft variation to the Code. Following a second round of public consultation, an Approval Report will be completed and the draft variation will be considered for approval by the FSANZ Board.

The FSANZ Board's decision will then be notified to the Ministerial Council. Following notification, the proposed draft variation to the Code is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.