



13 May 2011

[9-11]

APPLICATION A1049 – FOOD DERIVED FROM HERBICIDE-TOLERANT, HIGH OLEIC ACID SOYBEAN LINE MON87705 APPROVAL REPORT

Executive Summary

Main points are:

- **The Application seeks approval for food derived from glyphosate tolerant, high oleic acid soybean line MON87705, a genetically modified (GM) variety.**
- **Soybean MON87705 was developed for cultivation in soybean growing regions overseas, and once commercialised, could enter the food supply of Australia and New Zealand through imported food products.**
- **The Safety Assessment did not identify any potential public health and safety concerns.**
- **In accordance with GM labelling laws, food derived from MON87705 soybean, including the refined oil, must be labelled due to the altered nutrient profile.**
- **No major issues were raised in public submissions. General issues have been addressed in this report.**

Purpose

An Application was received from Monsanto Australia Ltd on 4 June 2010, seeking approval for food derived from herbicide-tolerant, high oleic acid soybean line MON87705 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code). This is a genetically modified (GM) variety that produces soybean oil with an altered fatty acid profile, which improves its oxidative stability for a range of food applications. Soybean oil derived from MON87705 has higher amounts of oleic acid, a monounsaturated fatty acid, and lower amounts of linoleic acid and certain saturated fatty acids, compared with conventional soybean oil. Soybean MON87705 is also tolerant to glyphosate herbicides. This Application was assessed under the General Procedure.

Safety Assessment

FSANZ has completed a comprehensive safety assessment of food derived from soybean line MON87705 (see **Supporting Document 1**¹).

¹ SD1 - Safety Assessment for Application A1049

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1049food4840.cfm>

This assessment included consideration of (i) the genetic modification to the plant; (ii) the potential toxicity and allergenicity of novel protein; (iii) the composition of soybean line MON87705 compared with that of conventional soybean varieties; and (iv) consideration of the nutritional impact of high oleic acid soybean oil.

The changes to fatty acid constituents in MON87705 soybean seed were achieved through RNA-based suppression of two endogenous genes encoding enzymes normally involved in fatty acid biosynthesis. As a result, oleic acid is increased from approximately 20% to approximately 70% of total fatty acids, with concomitant decreases in linoleic acid and stearic and palmitic acids in the seeds of the plant. Despite these changes, the fatty acid profile of MON87705 soybean oil is comparable to other commonly consumed vegetable oils such as canola and olive oils.

Tolerance to glyphosate in MON87705 soybean is conferred by the introduction of the *cp4 epsps* gene from *Agrobacterium* sp, strain CP4. FSANZ has previously assessed the CP4 EPSPS protein in the context of other glyphosate-tolerant crops and has concluded that its use raises no food safety concerns.

Based on the available evidence, including detailed studies provided by the Applicant, the conclusion from the safety assessment is that food derived from soybean line MON87705 is considered as safe and wholesome as food derived from other commercial soybean varieties.

Labelling

If approved, food derived from MON87705 soybean will be required to be labelled as 'genetically modified', irrespective of whether novel DNA or protein are present in the final food. Labelling of foods derived from MON87705 soybean, including refined oil, would be necessary because of the altered fatty acid composition of MON87705 seeds.

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. General labelling provisions for GM foods, based on the presence of novel DNA or protein in the final food or altered characteristics, provide consumers with information about the GM status of foods. Therefore, FSANZ considers that the general labelling requirements for GM foods, in addition to voluntary claim permissions relating to monounsaturated fatty acids, would provide consumers with adequate information on this product to enable an informed choice.

Impact of Regulatory Options

Following satisfactory completion of the safety assessment, two regulatory options were considered: (1) to reject the Application; or (2) to approve food derived from soybean line MON87705.

Following analysis of the potential costs and benefits of each Option on affected parties (consumers, the food industry and government), 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 and the subsequent development of a food regulatory measure, 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 a food regulatory measure developed as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure.
- 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.
- Any relevant New Zealand standards.
- Any other relevant matters.

Decision

To approve a variation to Standard 1.5.2 – Food produced using Gene Technology to include food derived from herbicide-tolerant, high oleic acid soybean line MON87705 in the Schedule.

Reasons for Decision

A variation to the Code giving approval to the sale and use of food derived from herbicide-tolerant, high oleic acid soybean line MON87705 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 herbicide-tolerant, high oleic acid soybean MON87705
- food derived from soybean line MON87705 is equivalent to other commercially available soybean varieties in terms of its safety for human consumption and nutritional adequacy
- labelling of all foods derived from soybean line MON87705 as genetically modified will be mandatory due to the altered nutrient profile
- a regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is a variation to the Code
- 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

As this Application was assessed as a General Procedure, one round of public consultation was conducted following the preparation of the Assessment Report. Comments were specifically requested on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from soybean line MON87705. Six submissions were received over the six-week consultation period. These are summarised in **Attachment 2** to this Report.

The main issues raised in public comments are discussed in the Approval Report.

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SUPPORTING DOCUMENT

The following material, which was used in the preparation of this Approval Report, is available on the FSANZ website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1049food4840.cfm>.

SD1: Safety Assessment Report (Approval): Application A1049 – Food derived from herbicide-tolerant, high oleic acid soybean line MON87705

INTRODUCTION

Monsanto Australia Ltd. submitted an Application on 4 June 2010, seeking approval for food derived from herbicide-tolerant, high oleic acid soybean line MON87705 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code). The genetic modification results in changes in the proportions of major fatty acids in soybean oil derived from MON87705: specifically increased levels of oleic acid with an associated decrease in levels of linoleic acid and saturated fatty acids, relative to conventional soybean oils.

The nutrient modification in MON87705 is achieved using a gene silencing mechanism to specifically down-regulate the expression in seeds of two endogenous genes encoding key enzymes, FATB and FAD2, involved in fatty acid biosynthesis. The resultant changes to fatty acids improve the oxidative stability of the oil and its nutrient profile, and are expected to broaden the range of food applications suited to soybean oil. Overall, MON87705 soybean oil has a fatty acid profile comparable to other widely consumed vegetable oils such as olive and canola oils.

Soybean MON87705 also contains a bacterial gene that confers tolerance in the plant to glyphosate-containing herbicides. This is achieved through the introduction of the *cp4 epsps* gene from the common soil bacterium, *Agrobacterium sp.* strain CP4. The glyphosate tolerance trait introduced into MON87705 plants has been described previously by FSANZ.

Soybean MON87705 has been developed for breeding into different soybean cultivars. As soybean is not a significant crop in Australia or New Zealand, there are currently no plans to produce any MON87705-containing cultivars for growing in Australia or New Zealand. Once commercialised, foods containing MON87705 soybean could enter the Australian and New Zealand food supply through imported products.

FSANZ completed a comprehensive scientific evaluation of MON87705 soybean according to FSANZ guidelines to assess the safety of the food for human consumption. The Assessment Report was released in February 2011 and public comment was sought on the safety assessment (**Supporting Document 1**) and proposed recommendations. Comments received were considered in the completion of this Approval Report.

1. The Issue / Problem

The Applicant has developed genetically modified (GM) soybean line MON87705 with an altered fatty acid profile and tolerance to glyphosate. Pre-market approval is necessary before food derived from this line may enter the Australian and New Zealand food supply. A variation to the Code granting approval to food derived from soybean line MON87705 must be approved by the FSANZ Board, and 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.

The Applicant has sought the necessary variation to Standard 1.5.2 to include food derived from soybean line MON87705 prior to any decision to commercialise the line. This Application has been assessed as a General 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 according to FSANZ guidelines. Foods that have been assessed under the Standard, if approved, are included in the Schedule to the Standard.

2.2 Overseas approvals

Regulatory submissions have been made to countries that import significant amounts of soybean, or food and feed products derived from US-grown soybean. The following table outlines the type of approval sought and the current status of the regulatory submission:

Country (Agency)	Submission Date	Registration Type	Status	Approval Date
US (FDA)	Nov-09	Food/Feed	Complete	20/1/11
US (USDA)	Jul-09	Environment	In progress	N/A
Canada (CFIA)	Dec-09	Feed/Environmental	In progress	N/A
Canada (HC)	Dec-09	Food	In progress	N/A
EU (EFSA)	Feb-10	Food/Feed	In progress	N/A
Japan (MAFF)	Jul-10	Feed	In progress	N/A
Japan (MAFF-MOE)	Jul-10	Environment	In progress	N/A
Japan (MHLW)	Jun-10	Food	In progress	N/A
Korea (KFDA)	Jul-10	Food	In progress	N/A
Korea (RDA)	Jul-10	Environment	In progress	N/A
Mexico (Health Ministry)	Dec-09	Food	In progress	N/A
Philippines (DA-BPI)	Jun-10	Food/Feed	In progress	N/A
Taiwan (DOH)	Aug-10	Food	In progress	N/A

A food and feed safety and nutritional assessment summary for MON87705 was submitted to the United States Food and Drug Administration (FDA) in November 2009, and approval was issued on 20 January 2011. A request for a Determination of Nonregulated Status for MON87705 including all progenies derived from crosses between MON87705 and other soybean varieties, from the United States Department of Agriculture – Animal and Plant Health and Inspection Service was made in July 2009.

Submissions may also be made to Ministry of Agriculture (MOA) in China. As appropriate, the Applicant will notify countries that import significant quantities of US soybean and soybean 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;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Assessment Questions

In completing this Assessment Report, the following questions were addressed:

- (i) Based on information provided by the Applicant on the nature of the genetic modification, the molecular characterisation, the characterisation of the novel protein, the compositional analysis and consideration of the nutritional issues, is food derived from soybean line MON87705 as safe for human consumption as food derived from conventional varieties of soybean?
- (ii) Is other information available, including from the scientific literature, general technical sources, independent scientists, other regulatory agencies, international bodies and the general community, that should be taken into account in this assessment?
- (iii) Are there any other considerations that would influence the outcome of this assessment?

RISK ASSESSMENT

Food derived from MON87705 soybean has been evaluated according to the safety assessment guidelines prepared by FSANZ (FSANZ, 2007) and a report is provided in **Supporting Document 1**. The summary and conclusions are presented below. In addition to information supplied by the Applicant, other available resource material including published scientific literature and general technical information was used in this assessment.

5. Risk Assessment Summary

5.1 Safety Assessment Process

The safety assessment of food derived from soybean line MON87705 included the following key elements: characterisation of the transferred coding sequences, 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 any newly expressed protein to be either allergenic or toxic in humans.

The assessment of MON87705 soybean was restricted to food safety and general nutritional issues. It does not address any potential risks related to the release into the environment of GM plants used in food production, the safety of animal feed or animals fed with feed derived from GM plants, or the safety of food derived from the non-GM (conventional) plant.

5.2 Outcomes of the Safety Assessment

Comprehensive molecular characterisation of MON87705 indicated that a functional two-gene suppression cassette and intact *cp4 epsps* gene co-integrated into the soybean genome at a single insertion site. The complete *FAD2-1A/FATB1-A* suppression cassette, under the control of a seed specific promoter, expresses an RNA that contains an inverted repeat of the soybean *fad2-1a* and *fatb1-a* gene segments. The RNA transcript forms a double-stranded RNA structure (hairpin) that suppresses endogenous *FATB* and *FAD2* RNA levels via RNA interference (RNAi) mechanisms, subsequently leading to the desired fatty acid phenotype. Expression of the *cp4 epsps* gene in chloroplasts confers tolerance to glyphosate containing herbicides. The genetic elements introduced into MON87705 were demonstrated to be stably integrated into the soybean genome. There are no antibiotic resistance marker genes present in soybean line MON87705.

Soybean MON87705 expresses one novel protein, CP4 EPSPS, which is expressed in seeds and other plant tissues. The average CP4 EPSPS content in seeds of MON87705 soybean is 110 µg/g dry weight. The safety of CP4 EPSPS has been assessed several times as a novel protein in glyphosate tolerant crops. Based on a dossier of studies and a history of use in GM crops, the CP4 EPSPS protein has been confirmed to lack any biologically significant sequence similarity to known protein toxins or allergens, and is readily degraded in conditions that simulate normal digestion. The evidence supports the conclusion that the CP4 EPSPS protein is neither toxic nor allergenic in humans.

Detailed compositional analyses of seeds harvested from MON87705 soybean, the isogenic control and a number of other commercial soybean varieties, confirm that oleic acid is significantly increased from approximately 23% in conventional soybean to around 76% (total fatty acids) in MON87705 soybean. The levels of linoleic acid are significantly decreased from 53% total fatty acids to approximately 10% in MON87705. In addition the saturated fatty acids, palmitic and stearic acids, comprise 6% of fatty acids in MON87705 compared with 15% in conventional soybean.

Except for the intended changes to four major fatty acids, the composition of MON87705 seed is comparable to that of the conventional soybean control. No significant differences between MON87705 and conventional soybean were observed from analysis of proximates, fibre, amino acids, key nutrients and anti-nutrients present in soybean. Comparisons of the composition of processed soybean fractions: refined, bleached and deodorised soybean oil, protein isolate and lecithin from MON87705 and conventional soybean varieties, confirmed the intended changes in the fatty acid profile of MON87705 soybean oil and did not reveal other differences of any biological or nutritional significance.

Dietary exposure assessments of the key fatty acids in MON87705 using consumption data from the United Kingdom and the United States indicated that substitution of MON87705 soybean oil for conventional soybean oil would result in higher intakes of the monounsaturated fatty acid, oleic acid, and marginally lower intakes of saturated fats normally found in soybean and other vegetable oils.

Two feeding studies using diets containing soybean meal prepared from MON87705, the conventional control and other conventional soybean varieties were conducted to compare the nutritional performance of MON87705 soybean with conventional varieties. A 90-day feeding study in rats and a 42-day study in broiler chickens both demonstrated that there were no differences between a diet containing MON87705 soybean meal and diets containing conventional soybean meal in terms of the ability of the diet to provide adequate nutrition to animals to support typical growth and wellbeing.

The safety of MON87705 soybean was further supported by the results of additional allergenicity studies that showed no difference in immunoglobulin binding between MON87705, the non-GM control and commercial soybean varieties. These results indicate that the levels of endogenous soybean allergens have not changed as a result of the genetic modification.

5.3 Conclusions

No potential public health and safety concerns were identified in the assessment of herbicide tolerant high oleic acid soybean MON87705. On the basis of the data provided in the present Application, and other available information, food derived from soybean MON87705 is considered as safe for human consumption as food derived from conventional soybean varieties.

RISK MANAGEMENT

6. Issues

6.1 Labelling

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. In accordance with general labelling provisions in Standard 1.5.2, foods derived from soybean line MON87705, if approved, would be required to be labelled as 'genetically modified'.

Whole soybean 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. In addition, in this case, refined soybean oil derived from MON87705 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).

Standard 1.5.2 also contains provision for additional labelling requirements in cases where the genetic modification has resulted in one or more significant composition or nutritional parameters having values outside the normal range of values for existing counterpart food not produced using gene technology (refer to clause 6). FSANZ has considered whether consumers should be alerted to the change in fatty acids, which would warrant an additional mandatory labelling statement to the effect that the food has been genetically modified to contain high levels of oleic acid.

FSANZ notes that following public education campaigns consumers are now more likely to have a better understanding of the terms, 'monounsaturated' and 'saturated' with regard to fats, than to have an understanding of individual fatty acids. There is potential for consumer confusion if mandatory labelling addresses specific fatty acids. Furthermore, the proposal to not require additional labelling for food derived from soybean line MON87705 is consistent with the approach taken for the recently approved high oleic acid soybean line DP-305423-1 (Application A1018).

Food derived from soybean line MON87705 may, however, meet the requirements for making a voluntary monounsaturated fatty acid claim, with respect to its oleic 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 monounsaturated fat nutrition claim is made in accordance with the definition of monounsaturated fatty acids (refer to clause 1 of Standard 1.2.8), the monounsaturated fatty acid content [subclause 5(7) of Standard 1.2.8] must be declared in the nutrition information panel. Voluntary monounsaturated fatty acid claims also trigger the requirement to declare *trans* fatty acids and polyunsaturated fatty acids in the nutrition information panel [subclause 5(4) of Standard 1.2.8].

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

6.2 Detection methodology

The Applicant is required to confirm that there is detection methodology for this GM food. PCR methods and protocols already exist to detect regulatory elements that are common to many GM foods and these may be used routinely as an initial screen for the presence of GM material. The complete nucleotide sequence of the inserted DNA and junction regions in MON87705 soybean is freely available information. Using this data, laboratories with expertise in polymerase chain reaction (PCR) analysis can readily develop an event-specific protocol for detecting novel DNA characteristic of MON87705 soybean that is directly applicable to the nature of the food in question, and that is appropriate for individual laboratory facilities.

7. Impact Analysis

In a letter to FSANZ dated 24 November 2010 (reference 12065), the Office of Best Practice Regulation (OBPR) provided an exemption from the need for FSANZ to inform the OBPR about several standards matters, including GM food applications made to FSANZ. This means that it is appropriate for FSANZ to consider any likely impacts based on generally available information. The impact analysis is designed to assist in the process of identifying the affected parties, any alternative options consistent with the objective of the proposed changes, and the potential impacts of any regulatory or non-regulatory options.

In this case, there are no non-regulatory options. The two regulatory options available for this Application are:

Option 1 – reject the Application, thus maintaining the *status quo*.

Option 2 – approve the proposed draft food regulatory measure to vary Standard 1.5.2 to permit the sale and use of food derived from herbicide-tolerant, high oleic acid soybean line MON87705 in the Schedule to the Standard.

7.1 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, including food importers and distributors, processors and manufacturers, and food retailers.
- Government generally, including food regulation enforcement agencies.

7.2 Benefit Cost Analysis

FSANZ has a statutory obligation under s 29 of the FSANZ Act to consider the costs and benefits of both regulatory options. This section is not intended to be an exhaustive, quantitative dollar analysis of the options and, in fact, most of the impacts that are considered cannot be assigned a dollar value. Rather, the analysis seeks to highlight the qualitative impacts of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

7.2.1 Option 1 – Reject the Application

Consumers: Possible restriction on some imported food products if they contained derivatives of soybean line MON87705.

No impact on consumers wishing to avoid GM foods, as food from soybean MON87705 is currently not permitted.

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 food products once soybean line MON87705 is commercialised overseas.

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

7.2.2 Option 2 – Approve a draft regulatory measure

Consumers: No restriction on imported foods containing soybean line MON87705.

Labelling of all food products derived from MON87705 soybean, including RBD soybean oil, would allow consumer choice.

Government: No potential for trade disruption on regulatory grounds if soybean line MON87705 was used in imported processed foods that were manufactured overseas.

Approval of soybean line MON87705 would ensure no conflict with WTO responsibilities.

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

Industry: Importers of processed foods containing soybean derivatives would benefit as foods derived from MON87705 would be compliant with the Code, allowing broader market access and increased choice in raw materials.

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

Possible cost to food industry as foods derived from soybean line MON87705 would be required to be labelled.

7.3 Comparison of Options

As food from soybean line MON87705 has been assessed as being as safe as food from conventional soybean varieties, 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 soybean line MON87705 by other countries could result in restrictions on certain imported soybean products in the Australian and New Zealand markets.

The need to segregate any products containing soybean line MON87705 from those containing approved soybean varieties could increase the costs of imported foods.

Based on the conclusions of the safety assessment, the potential benefits of Option 2 outweigh the potential costs. A variation to Standard 1.5.2 giving approval to herbicide-tolerant, high oleic acid soybean line MON87705 is therefore the preferred option.

As soybean is not a significant crop in Australia or New Zealand, there are currently no plans to produce any MON87705-containing cultivars for growing in Australia or New Zealand. Cultivation in Australia or New Zealand could have an impact on the environment, which would need to be independently assessed by the Office of the Gene Technology Regulator (OGTR) in Australia, and the Environmental Risk Management Authority (ERMA) in New Zealand before commercial release in either country could be permitted.

COMMUNICATION AND CONSULTATION STRATEGY

8. Communication

This Application is considered a routine matter and therefore FSANZ applied a basic communication strategy. As normally applies to all applications, the Assessment and Approval Reports will be publically available on the FSANZ website. Public comment on the assessment was sought prior to preparation of the Approval Report. The Applicant and individuals and organisations that made submissions on this Application were notified at each stage of the assessment.

This Approval Report and the decision of the FSANZ Board to approve the draft variation to Standard 1.5.2, if made, has been notified to the Ministerial Council.

If the approval of food derived from herbicide-tolerant, high oleic acid soybean line MON87705 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.

9. Consultation

As a General Procedure, this Application was subject to one round of public consultation. Comments were specifically sought on the scientific aspects of this Application, in particular, information relevant to the safety of food derived from MON87705 soybean.

The Assessment Report, including the proposed draft variation to the Code, was advertised for public comment over a six-week period between 14 February and 28 March 2011. Six submissions were received, and a summary is provided in **Attachment 2** to this Report. Where appropriate, FSANZ has addressed requests for clarification or updated information through making minor changes to the relevant sections of this Report.

9.1 General issues

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 relevant 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. Public consultation periods are considered integral to this process, and comments received from submitters contribute to the overall effectiveness of the risk assessment.

9.2 Specific issues

9.2.1 Dietary intake assessment

It was noted by MAF that a dietary intake assessment relevant to New Zealand and Australian populations was not included in the assessment of MON87705 soybean.

9.2.1.1 Response

FSANZ has previously undertaken dietary modelling for high oleic acid soybean with a similar nutrient profile to MON87705 soybean (see Dietary Intake Assessment for Application A1018). This assessment determined that soybean oil specifically is not a major contributor to edible oil intakes in New Zealand and Australian populations. Moreover, the nutrient changes in MON87705 soybean, while expanding possible food uses of soybean oil, are unlikely to result in significant changes to overall dietary intakes of edible oils.

In terms of specific fatty acids, major dietary contributors to oleic and linoleic acid intakes across both Australian and New Zealand populations were identified as dairy products (excluding butter and butter fats), edible oils (for example, olive oil), fruits and vegetables, breads and bakery products, and meat and meat products. Based on this previous modelling, dietary intakes of oleic or linoleic acids would not be altered to any great extent by approval of high oleic acid soybean (up to 6% increase for oleic acid and up to 10% decrease for linoleic acid). Many different types of edible vegetable oils are available to consumers and the food industry, including those with altered nutrient profiles as a result of traditional plant breeding. In addition, scenario modelling necessarily over-represents possible impacts on nutrient intakes. Given the similarities in nutrient profiles of high oleic acid soybean lines, FSANZ does not consider that further discussion of potential dietary impact is warranted for this Application.

9.2.2 Fatty acid composition

The safety assessment of MON87705 soybean seed did not report on fatty acids that were below the limit of quantitation (LOQ) of the assay system. MAF noted that the compositional analysis of high oleic acid soybean line DP-305423-1 (Application A1018) included a broad range of fatty acids, compared with the nine fatty acids reported in the safety assessment of MON87705 soybean. Noting that the levels of C17:0 and C17:1 fatty acids were slightly elevated in soybean oil from DP-305423-1, MAF suggested that these should also be reported for MON87705 soybean, together with details on the LOQ of the assay system used in the compositional studies.

9.2.2.1 Response

The Applicant provided data on the analysis of 26 fatty acids (C8 to C24) in soybean seed from MON87705, Asgrow A3525 (parental line) and 19 commercial soybean varieties grown at the same time in various combinations at five separate field sites (MSL0021756).

The method of fatty acid analysis involved lipid extraction, conversion to methyl esters and analysis by gas chromatography. The limit of quantitation of this assay system was 0.0200%. For the combined site data, the statistical analysis excluded components with greater than 50% of observed results below the LOQ. This process resulted in the exclusion of fatty acids as follows: C8:0, C10:0, C12:0, C14:0, C14:1, C15:0, C15:1, C16:1, C17:0, C17:1, C18:1, C18:2, C18:3, C20:2, C20:3 and C20:4².

Otherwise, for statistical purposes, results below the LOQ were assigned a value equal to half the LOQ. This applied only to some measurements of lignoceric acid (C24:0), which were assigned a value of 0.010%. The nine fatty acids reported in the safety assessment account for 100% of the fatty acids in MON87705 soybean oil.

9.2.3 Commercial uses of high oleic acid soybean oil

FSANZ was asked to clarify the possible food uses of high oleic acid soybean MON87705, particularly as it was noted in submissions that other high oleic acid vegetable oils are available.

9.2.3.1 Response

High oleic acid soybean oil produced from MON87705 has a fatty acid profile that has reduced saturated fats, and higher monounsaturated fat. These properties, particularly the reduction in polyunsaturated fats (18:2), result in increased oxidative stability, which greatly improves the performance of the oil in frying and baking applications. The decrease in saturated fatty acids (16:0, 18:0) is also considered to improve the nutritional profile of the oil for use in food preparation.

Subject to regulatory approvals, the Applicant advises that MON87705 will be conventionally bred into Vistive™ low-linolenic soybean, further improving the oil profile by lowering the level of linolenic acid and eliminating the need to hydrogenate the oil. Vistive™ low-linolenic soybean was developed by the Applicant through conventional plant breeding to produce lower levels of linolenic acid³. This allows food companies to avoid hydrogenation of soybean oil, helping to reduce or eliminate undesirable *trans* fatty acids from the diet.

² Of a total of 86 samples analysed for each fatty acid, between 77 and 86 of these samples (ie. 90 – 100%) were below the LOQ of the assay.

³ Vistive™ low-linolenic soybean has a mutation in the *Fad3-1c* and *Fad3-1b* genes that result in reduced levels of linolenic acid.

The Vistive™ low-linolenic soybean oil is currently commercially sold in the USA. Soybean oil from MON87705 combined with the Vistive™ low-linolenic soybean background has the following specification: palmitic acid (< 4.0%); stearic acid (< 4.0%); oleic acid (55 - 85%); linoleic acid (8 – 30%); and linolenic acid (< 4.0%). The Applicant considers that these fatty acid modifications enable soybean oil to be used as an alternative to other vegetable oils currently available, and offers the opportunity to reduce the practice of blending oils, which has become the solution for frying applications to avoid *trans* fatty acids.

In addition, the decreased saturated fatty acids coupled with the expected increased stability of MON87705 soybean oil, make it particularly suited for use in bottled vegetable oil, salad dressings, margarine and other similar food products for which conventional soybean oil is used. It is anticipated that MON87705 soybean oil could substitute for traditional liquid soybean oil in the market place. Liquid soybean oil is mainly used in salad dressings, mayonnaise and margarines, as well as for domestic cooking. These four food categories represent approximately 94% of the replaceable liquid soybean oil market in the United States.

9.3 World Trade Organization

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

The inclusion of food derived from herbicide-tolerant, high oleic acid soybean line MON87705 in the Code would have a trade-liberalising 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. For this reason, notification of this Application as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Agreement on the Application of SPS Measures was not necessary.

CONCLUSION

10. Conclusion and Decision

Decision

To approve the variation to Standard 1.5.2 – Food produced using Gene Technology, to include food derived from herbicide-tolerant, high oleic acid soybean line MON87705 in the Schedule.

10.1 Reasons for Decision

A variation to the Code giving approval to the sale and use of food derived from herbicide-tolerant, high oleic acid soybean line MON87705 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 herbicide-tolerant, high oleic acid soybean MON87705
- food derived from soybean line MON87705 is equivalent to other commercially available soybean varieties in terms of its safety for human consumption and nutritional adequacy

- labelling of all foods derived from soybean line MON87705 as genetically modified will be mandatory due to the altered nutrient profile
- a regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the preferred option is a variation to the Code, and
- there are no other measures that would be more cost-effective than a variation to Standard 1.5.2 that could achieve the same end.

11. Implementation and Review

The FSANZ Board's decision on this Approval Report will be notified to the Ministerial Council. Subject to a request from the Ministerial Council for a review of FSANZ's decision, the proposed variation to the Code is expected to come into effect on gazettal.

References

FSANZ (2007) *Safety Assessment of Genetically Modified Foods – Guidance Document*. Document prepared by Food Standards Australia New Zealand.
http://www.foodstandards.gov.au/srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf.

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 sunseting

Commencement: On gazettal

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

	7.8	Food derived from herbicide-tolerant high oleic acid soybean line MON87705	
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Summary of Public Submissions on Assessment Report

Submitter	Comments
Department of Health, Victoria	<ul style="list-style-type: none"> ▪ Supports approval of the Application (Option 2).
Australian Food and Grocery Council (AFGC)	<ul style="list-style-type: none"> ▪ Supports approval of the Application, stating that approval would allow industry to make independent commercial decisions on whether to use this product. ▪ Supports current labelling provisions that would require high oleic acid soybean oil derived from MON 87705 to be labelled as 'genetically modified', because of the altered nutrient profile.
Food Policy and Programs Branch, South Australia Health	<ul style="list-style-type: none"> ▪ Supports approval of the Application (Option 2). ▪ Considers that there is a need for additional mandatory labelling of high oleic acid soybean oil derived from MON 87705, to inform consumers of the nutrient change. Suggested wording for labelling purposes is: "this food has been genetically modified to contain high levels of oleic (monounsaturated) fat in comparison to conventional soybean oil". ▪ Notes that additional labelling was not required for high oleic acid soybean oil derived from DP-305423-1 (Application A1018). While acknowledging the need for consistency in labelling, suggests further consideration should be given to informing consumers about altered nutrient profiles, particularly as these types of traits are becoming more common.
Ministry of Agriculture and Forestry (formerly New Zealand Food Safety Authority)	<ul style="list-style-type: none"> ▪ Suggests that the molecular characterisation section of the Safety Assessment should provide more detailed explanation of gene silencing mechanisms utilising RNAi, and further elaborate the rationale for using the two T-DNA transformation process. ▪ Suggests that further technical information is required to demonstrate that the purified CP4 EPSPS protein used to evaluate potential toxicity and allergenicity is biochemically equivalent to the novel protein expressed in MON87705 soybean. ▪ Considers that the Safety Assessment should have included a discussion of the potential dietary impact of high oleic acid soybean on Australian and New Zealand populations. ▪ States that the possible food uses of high oleic acid soybean oil derived from MON 87705 should be clarified, as the proposed uses differ from those stated in the assessment of high oleic acid soybean DP-305423-1 (Application A1018). ▪ Notes that the range of fatty acids reported appears to be less comprehensive than that reported in the assessment of high oleic acid soybean DP-305423-1 (Application A1018).

Submitter	Comments
Complementary Healthcare Council	<ul style="list-style-type: none"> ▪ Expresses general support for this Application, and for the labelling of oil derived from MON 87705 because of the nutrient change, which should provide consumers with adequate information to allow informed choice. ▪ Notes that cultivation of MON 87705 soybean in Australia would require assessment and approval from the Gene Technology Regulator. ▪ Encourages a sustainable complementary food product industry and does not support any restrictions to international trade on soybeans.
Queensland Government	<ul style="list-style-type: none"> ▪ Expresses general support for technologies that do not harm human health or the environment. ▪ Seeks updated information on the regulatory status of MON 87705 soybean in the USA, and other countries where permission to import has been sought. ▪ Requests detection methodology be provided to Queensland Health Forensic and Scientific Services. ▪ Seeks to know the advice provided by FSANZ to the Office of Best Practice Regulation about this Application. ▪ Notes that the safety assessment relied on Monsanto Study Reports and, as a result, considers that the assessment could be seen as not being independent.