



14 February 2011
[3-11]

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

Executive Summary

Purpose

An Application was received from Monsanto Australia Ltd on 4 June 2010, seeking a variation to Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code), to permit food derived from herbicide-tolerant high oleic acid soybean line MON87705. This is a genetically modified (GM) soybean 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 herbicides containing glyphosate.

This Application is being assessed under the General Procedure and will include one round of public consultation.

Safety Assessment

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

¹ SD1 - Safety Assessment for Application A1041
<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1049food4840.cfm>

Tolerance to glyphosate herbicide 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. Comprehensive labelling of foods derived from MON87705 soybean, including refined soybean oil, would be necessary because of the introduced changes in the fatty acid composition of MON87705 seeds.

There is potential for consumer confusion if mandatory labelling were to be applied to differentiate specific fatty acids such as '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 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 monounsaturated 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. 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.

Impact of Regulatory Options

Following satisfactory completion of the safety assessment, two regulatory options were considered: (1) not to approve the Application; or (2) approval of 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.

Preferred Approach

Develop a draft 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 Preferred Approach

The development of a draft 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 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 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

Public submissions are now invited on this Assessment Report. Comments are requested on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from soybean line MON87705.

As this Application is being assessed as a General Procedure, there will be one round of public comment. Responses to this Assessment Report will be used to develop the Approval Report for the Application.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations 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) 28 March 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 DOCUMENT

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/applicationa1049food4840.cfm>

SD1: Safety Assessment Report: 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 decreased levels of saturated fatty acids, and increased levels of oleic acid with an associated decrease in linoleic acid, relative to conventional soybean oils.

The nutritional 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 nutritional 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 comMONsoil 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.

This Assessment includes a full scientific evaluation of food derived from herbicide-tolerant, high oleic acid soybean line MON87705 according to FSANZ guidelines (FSANZ, 2007) to assess its safety for human consumption. Public comment is now sought on the safety assessment (**Supporting Document 1**) and proposed recommendations prior to further consideration and completion of the Application.

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. The Application is being 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

A food and feed safety and nutritional assessment summary for MON87705 was submitted to the United States Food and Drug Administration (FDA) in October 2009. 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.

Regulatory submissions have been, or will be, made to a number of countries that import significant soybean, or food and feed products derived from US-grown soybean and have functional regulatory systems in place. In addition, submissions may be made to Ministry of Agriculture (MOA) in China, Ministry of Health, Labor and Welfare (MHLW) and Ministry of Agriculture, Forestry and Fisheries (MAFF) in Japan, the Korean Food and Drug Administration (KFDA) and the Rural Development Administration (RDA) of the Canadian Food Inspection Agency (CFIA) and Health Canada, and the European Food Safety Authority (EFSA). 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

In accordance with general labelling provisions in Standard 1.5.2, food 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 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).

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 to alert consumers to the change in fatty acid profile, such as an additional mandatory labelling statement to the effect that the food has been genetically modified to contain high levels of oleic 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, 'monounsaturated' 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.

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].

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

6.2 Detection methodology

As part of the Application, the Applicant is required to confirm that there is detection methodology for the GM food. For MON87705 soybean, the complete nucleotide sequence of the inserted DNA and junction regions has been provided without confidentiality restrictions. This would enable specialist laboratories experienced in polymerase chain reaction (PCR) analysis to develop an event-specific protocol for the detection of novel DNA characteristic of MON87705 soybean. 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.

7. Options

The impact analysis represents likely impacts based on 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 provisions. The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010 (reference 12065) provided an exemption from the need of the OBPR to be informed about GM food applications made to FSANZ.

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

Reject the Application, thus maintaining the *status quo*.

7.2 Option 2 – Develop 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 herbicide-tolerant, high oleic acid soybean line MON87705 in the Schedule to the Standard.

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

8.2 Benefit Cost Analysis

This section is not intended to be an exhaustive, quantitative dollar analysis of the regulatory 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.

8.2.1 Option 1 – Reject the Application

Consumers: Possible restriction in the availability of some imported food products if they contained 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.

8.2.2 Option 2 – Develop 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.

8.3 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.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

This Application is considered a routine matter and therefore FSANZ has applied a basic communication strategy. This involves advertising the availability of assessment reports for public comment in the national press and making reports available 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. If the draft variation to the Code is approved by the FSANZ Board, that decision will be 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.

10. Consultation

Public submissions are invited on this Assessment Report and the proposed change to the Code. Comments are specifically sought on the scientific aspects of this Application, in particular, information relevant to the safety of food derived from soybean line MON87705.

10.1 World Trade Organization (WTO)

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 is not necessary.

CONCLUSION

11. Conclusion and Preferred Approach

Preferred Approach

Develop a draft 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.

11.1 Reasons for Preferred Approach

The development of a draft 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 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, 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.

12. Implementation and Review

Following the consultation period for this document, 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 be notified to the Ministerial Council. 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*. Document prepared by Food Standards Australia New Zealand.
http://www.foodstandards.gov.au/srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf.

Attachment

1. Draft Variation to the *Australia New Zealand Food Standards Code*

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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