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

11 September 2009
[15-09]

APPLICATION A1018
FOOD DERIVED FROM HIGH OLEIC ACID SOYBEAN LINE DP-305423-1
ASSESSMENT REPORT

Executive Summary

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from Pioneer Hi-Bred International, Inc. (Pioneer), a DuPont Company, on 22 September 2008. The Applicant requested 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 a new genetically modified (GM) variety of soybean, high oleic acid soybean line DP-305423-1.

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

Safety Assessment

Soybean line DP-305423-1 has been genetically modified (GM) with a partial gene sequence (fragment) designed to decrease the expression of the endogenous soybean fatty acid desaturase gene (*gm-fad2-1*). This leads to the production of seeds that have a higher concentration of oleic acid (C18:1) and a correspondingly lower concentration of linoleic acid (C18:2). The purpose of this change in fatty acid profile is to provide a stable vegetable oil that is suitable for frying applications without the need for hydrogenation. Soybean line DP-305423-1 also contains a modified version of a soybean acetolactate synthase (*als*) gene (*gm-hra*). The GM-HRA enzyme can function in the presence of the ALS-inhibiting class of herbicides, thereby conferring a degree of tolerance to those herbicides. However, the transcript of this gene was used as a selectable marker to identify genetically modified plants during their initial development in the laboratory and commercial levels of herbicide tolerance have not been conferred on soybean 305423.

FSANZ has completed a comprehensive safety assessment of food derived from soybean line DP-305423-1 (see **Supporting Document 1**[1]).

[1] SD1 Safety Assessment for A1018

This assessment included consideration of (i) the genetic modification to the plant; (ii) the potential toxicity and allergenicity of the novel proteins; and (iii) the composition of soybean DP-305423-1 compared with that of conventional soybean varieties. The potential nutritional impact of the altered fatty acid profile was also assessed.

No public health and safety concerns have been identified in this pre-market safety assessment of food derived from soybean DP-305423. On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from high oleic acid soybean line DP-305423-1 is considered as safe and wholesome as food derived from other commercial soybean varieties.

Labelling

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. The general labelling requirements will provide consumers with information about the GM status of foods.

In accordance with general labelling provisions, food derived from high oleic acid soybean line DP-305423-1, if approved, would be required to be labelled as genetically modified if novel DNA and/or novel protein is present in the final food. Studies conducted by the Applicant show that a novel protein is present in the seed.

In addition to this, however, is the consideration that soybean DP-305423-1 has been significantly changed with respect to its fatty acid profile, having intentionally elevated levels of oleic acid and reduced levels of linoleic acid. Clause 7(a) of Standard 1.5.2 of the Code states that labelling or other information requirements may be specified 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.* FSANZ has considered this issue and is recommending that the label of any food, including oil, derived from soybean line DP-305423-1 must only include a statement that the food has been genetically modified. Specific labelling to indicate the changes in concentrations of oleic acid and linoleic acid are not considered to be informative for consumers as there is no significant change to the overall level of unsaturated fatty acids in the soybean oil. In this context, additional labelling for individual fatty acid changes is likely to be confusing and potentially misleading to consumers.

Impact of regulatory options

Following satisfactory completion of the safety assessment, two regulatory options were considered: (1) rejection of the Application; or (2) approval of food derived from soybean DP-305423-1.

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 or varied as a result of the Application/Proposal 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 including for residue limits (see Section 6.1)

- Any other relevant matters

Preferred Approach

Develop a food regulatory measure, to amend Standard 1.5.2 – Food produced using Gene Technology, to include food derived from high oleic acid soybean line DP-305423-1 in the Table to clause 2.

Reasons for Preferred Approach

The development of a draft amendment to the Code to give approval to the sale and use of food derived from high oleic acid soybean line DP-305423-1 in Australia and New Zealand is proposed on the basis of the available scientific evidence, for the following reasons:

- the safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce high oleic acid soybean line DP-305423-1

- seed from high oleic acid soybean line DP-305423-1 contains elevated levels of oleic acid and reduced levels of linoleic acid, when compared to conventional soybean, but is equivalent to other commercially available soybean varieties in terms of its safety for human consumption and nutritional adequacy

- labelling of certain foods derived from high oleic acid soybean line DP-305423-1 will be required if novel DNA, novel protein and/or altered levels of oleic and linoleic acid are present in the final food

- 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, an amendment 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 DP-305423.

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 variation to the Code 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 Standards Development 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) 23 October 2009

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) 473 9942

CONTENTS

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/standardsdevelopment/applications/applicationa1018food4091.cfm

SD1: Safety Assessment Report: Application A1018 – Food Derived from High Oleic Acid Soybean Line DP-305423-1

INTRODUCTION

On 22 September 2008, Pioneer Hi-Bred International, Inc. (Pioneer), a DuPont Company, submitted an Application seeking approval for food derived from high oleic acid soybean line DP-305423-1 (also referred to as soybean 305423) under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

Soybean 305423 has been genetically modified (GM) with a partial gene sequence (fragment) designed to decrease the expression of the endogenous soybean fatty acid desaturase gene (*gm-fad2-1*). This leads to the production of seeds higher in oleic acid (C18:1) and correspondingly lower in linoleic acid (C18:2). Soybean 305423 also contains a modified version of a soybean acetolactate synthase (*als*) gene (*gm-hra*), conferring a degree of tolerance to the ALS-inhibiting class of herbicides (e.g. the sulfonylureas). This gene was used as a selectable marker to identify genetically modified plants during their initial development in the laboratory and commercial levels of herbicide tolerance have not been conferred on soybean 305423.

For cooking purposes, conventional soybean oil has undesirable thermal and oxidative stability due predominantly to the presence of linoleic acid. When heated such oil develops qualities that negatively influence flavour and cooking quality. Conventional chemical processing to reduce levels of linoleic acid, such as through partial hydrogenation, in which carbon double bonds are reduced, enables oxidative stability to be achieved but it also leads to the formation of undesirable *trans* fatty acids. Thus the conventional soybean oil is unsatisfactory both in the natural and hydrogenated forms. The Applicant claims that high oleic acid soybean oil may therefore be used for a number of food applications, including deep fat frying, while also potentially offering improved nutritional properties compared to conventional oil or partially hydrogenated oil.

This Assessment includes a full scientific evaluation of food derived from soybean 305423 according to FSANZ guidelines[2] to assess its safety for human consumption. Public comment is now sought on the safety assessment and proposed recommendations prior to further consideration and completion of the Application.

1. The Issue / Problem

The Applicant has developed GM soybean 305423 whose seeds contain more oleic acid than conventional soybeans. The line also contains a gene conferring a degree of resistance to herbicides such as the sulfonylureas. Pre-market approval is necessary before this product may enter the Australian and New Zealand food supply. An amendment to the Code granting approval to food derived from soybean 305423 must be approved by the FSANZ Board, and subsequently notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). An amendment to the Code may only be gazetted once the Ministerial Council process has been finalised.

The Applicant has already obtained approval to grow soybean 305423 in several countries and is also seeking food approval for soybean 305423 in key trading markets for soybean, including Australia and New Zealand. The Applicant has therefore sought the necessary amendments to Standard 1.5.2 to include food derived from soybean line DP-305423-1 prior to any decision to commercialise this line. The Application is being assessed as a General Procedure.

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

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 listed in the Table to clause 2 of the Standard.

2.2 Overseas approvals

Submissions on soybean line DP-305423-1 have been made to the appropriate agencies for food, feed and environmental approvals in the United States (Food and Drug Administration, Department of Agriculture), Canada (Health Canada and the Canadian Food Inspection Agency), Japan (Ministry of Health, Labour and Welfare, Ministry of Agriculture, Forestry and Fisheries) and Korea (Rural Development Administration, Korea Food and Drug Administration). The U.S. Food and Drug Administration completed its regulatory review in January 2009[3]. Health Canada and the Canadian Food Inspection Agency[4] approved Soybean DP-305423-1, for cultivation and food and feed use in Canada, in May 2009. Regulatory submissions for food import approvals have also been made in Mexico and the European Union[5]. The Applicant has advised that further submissions for import approvals in other key international markets will also be made.

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;

[3] FDA (2009) *Biotechnology Consultation Note to the File BNF No. 000110*. Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration. http://64.26.159.139/docroot/decdocs/09-052-002.pdf. Accessed on 24 April 2009.

[4] CFIA (2009) *Decision Document DD2009-76: Determination of the Safety of Pioneer Hi-Bred Production Ltd.'s Soybean (Glycine max (L.) Merr.) Event 305423*. Canadian Food Inspection Agency. http://www.inspection.gc.ca/english/plaveg/bio/dd/dd0976e.shtml. Accessed on 27 May 2009

[5] Pioneer Hi-Bred International Inc. (2007) *Summary of the Application for Authorisation of Genetically Modified 305423 Soybean and Derived Food and Feed in Accordance with Regulation (EC) 1829/2003*. European Food Safety Authority. http://www.gmo-compass.org/pdf/regulation/soybean/305423_soybean_application_foo_feed.pdf. Accessed on 23 April 2009. COGEM (2007) *Import and Processing of Herbicide Tolerant Soybean 305423: COGEM Advice CGM/071219-03*. Commissie Genetische Modificatie, Netherlands. http://www.cogem.net/ContentFiles/071219-03%20advies%20soja%20305423%20import2.pdf. Accessed on 23 April 2009.

- the promotion of fair trading in food; and

- any written policy guidelines formulated by the Ministerial Council.

4. Questions to be answered

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 any nutritional issues, is food derived from soybean line DP-305423-1 comparable to food derived from conventional varieties of soybean in terms of its safety for human consumption?

Is other information available, including from the scientific literature, general technical information, independent scientists, other regulatory agencies and 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 high oleic acid soybean line DP-305423-1 has been evaluated according to the safety assessment guidelines prepared by FSANZ[6] and is provided in **Supporting Document 1**. The summary and conclusions from the safety assessment 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

In conducting a safety assessment of food derived from soybean 305423, a number of criteria have been addressed including: a 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(s) to be either allergenic or toxic in humans.

The safety assessment applied to food from soybean 305423 addresses only food safety and nutritional issues. It does not address any 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

Soybean 356043 contains two introduced coding sequences (and associated regulatory elements), *a gm-fad2-1* partial sequence and a complete *gm-hra*.gene. Detailed molecular analyses indicate that there are 4 insertion sites at a single genetic locus.

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

These sites contain multiple copies, both intact and truncated, of the *gm-fad2-1* partial sequence and a single copy of the *gm-hra* gene. Breeding over three generations has confirmed stability of the introduced genetic elements and segregation data indicate their Mendelian inheritance. No antibiotic resistance marker genes are present in soybean 305423.

Since the introduced *gm-fad2-1* element is a partial sequence rather than a complete gene, a functional protein is not produced during its transcription in cells of soybean 305423. However, the effect of transcription of the partial sequence is to suppress expression of the endogenous *gm-fad2-1* gene which, in turn, leads to a reduction in formation of linoleic acid from oleic acid and a concomitant accumulation of oleic acid.

Soybean 305423 expresses one novel protein, GM-HRA. This protein is a modified version of the native ALS from soybean. The GM-HRA protein is characterised by two specific amino acid changes in the mature ALS protein that are known to confer tolerance to sulfonylurea herbicides. The GM-HRA protein is 656 amino acids in length with a predicted molecular weight of 71 kDa. Following transport into the chloroplast and cleavage of the transit peptide, the mature protein is 604 amino acids with a predicted molecular weight of 65 kDa. The GM-HRA protein is expressed at low levels in soybean 305423 seed, with a mean concentration of 2.5 ng/mg dry weight (range 0-4.9 ng/mg).

The GM-HRA protein conforms in size and amino acid sequence to that expected, does not exhibit any post-translational modification including glycosylation, and also demonstrates the predicted enzymatic activity.

Bioinformatic studies with the GM-HRA protein confirm the absence of any biologically significant amino acid sequence similarity to known protein toxins or allergens. Digestibility studies have demonstrated that the protein would be rapidly degraded following ingestion, similar to other dietary proteins, and a thermolability study has shown that the protein is inactivated after incubation for 15 minutes at 50^{o}C and would therefore not survive standard cooking/processing procedures. An acute oral toxicity study in mice confirmed the absence of toxicity. Taken together, the evidence indicates that the GM-HRA protein is neither toxic nor likely to be allergenic in humans.

Compositional analyses were done to establish the nutritional adequacy of soybean 305423, and to compare it to a non-transgenic conventional soybean under typical cultivation conditions. The mean oleic acid (C18:1) content has been increased from 21.1% in the control soybean to 76.5% in soybean 305423. Since the level of oleic acid in soybean 305423 oil is comparable to that in a range of other commercially available vegetable oils, no safety concerns are raised. The linoleic acid (C18:2) and linolenic acid (C18:3) contents have been concomitantly decreased from a mean level of 52.5% to a mean level of 3.62% for linoleic acid and from 9.35% to 5.39% for linolenic acid. The level of C18:3 in soybean 305423, while significantly lower than that in the control is, nonetheless within the normal range found in soybeans while the level of C18:2 in soybean 305423 is outside the normal range. These changes are consistent with the intended outcome of inserting the *gm-fad2-1* partial sequence into soybean 305423.

An unintended result of the genetic modification is an increase in levels of heptadecanoic acid (C17:0) and heptadecanoic acid (C17:1) in soybean 305423. These two fatty acids together constitute around 2% of the total fatty acid content in soybean 305423, compared to 0.17% in the conventional counterpart. A survey of dietary sources of these two acids shows that both are consumed in a normal human diet and are also readily metabolised. The increased levels of C17:0 and C17:1 therefore raise no safety concerns.

In terms of other analytes, seeds of soybean 305423 were found to be compositionally equivalent to those from the non-GM parent and other non-GM commercial soybean cultivars. Several minor differences in key nutrients and other constituents were found but the mean levels observed are within the range of values observed for the non-transgenic comparator and within the range of natural variation.

Soybean is one of the major allergenic foods. The potential allergenicity of soybean 305423 was compared to that of the parental soybean variety by assessing IgE binding responses using sera from known soybean allergic patients. These studies indicated that soybean 305423 does not have any greater potential to be allergenic than conventional soybean varieties.

Dietary exposure assessments of the fatty acids contained in soybean indicate that the substitution of soybean oil with oil from soybean 305423 would have minimal effect on the intake of dietary significant fatty acids. At most, if soybean oil was replaced with the oil derived from soybean 305423, there may be a marginal increase (up to 6%) in intake of oleic acid and a marginal decrease (up to 10%) in linoleic acid intake. In terms of both cooking quality and nutrition, the replacement of linoleic acid by oleic acid means that partial hydrogenation is not required to stabilise the fatty acids. This in turn, has the potential to reduce the intake of undesirable *trans* fats in the diet. Taken overall, it is concluded that use of oil from soybean 305423 would have minimal nutritional impact. This conclusion is consistent with that reached by FSANZ for a previous high oleic acid soybean application (FSANZ, 2000)[7].

Although not essential for establishing the safety of the food, two animal feeding studies with the high oleic acid soybeans were evaluated as additional supporting data. Such studies are not toxicity studies and are intended to address only whether food derived from the GM plant is able to sustain normal growth and well being. These studies demonstrated that the high oleic acid soybeans are equivalent to non-GM soybeans in their ability to support typical growth and well-being, thus confirming the nutritional adequacy of seeds from soybean 305423.

Based on the above findings, the introduction of high oleic acid soybean 305423 into the food supply would not be expected to have any adverse nutritional impact. This was supported by the results of two feeding studies with broiler chickens and rats, where no differences in health and growth performance were found between animals fed diets containing soybean 305423 meal and those fed conventional soybean meal diets.

5.3 Conclusion

No potential public health and safety concerns have been identified in the assessment of high oleic acid soybean 305423. On the basis of the data provided in the present Application, and other available information, food derived from soybean 305423 is considered as safe for human consumption as food derived from conventional soybean cultivars.

[7] FSANZ (2000) *Application A387: Food Derived from High Oleic Acid Soybean Lines G94-1, G94-19 and G168*. Report prepared by Australia New Zealand Food Authority (now Food Standards Australia New Zealand). http://www.foodstandards.gov.au/_srcfiles/A387_FAR.pdf.

RISK MANAGEMENT

6. Issues raised

6.1 Risk Management Strategy

If approved, food derived from high oleic acid soybean line DP-305423-1 will be required to be labelled as genetically modified if novel DNA and/or novel protein is present in the final food. Studies conducted by the Applicant show that a novel protein is present in the seed.

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.' As the purpose of the genetic modification was to reduce the linoleic acid concentration of the oil and the change is significant, oil derived from soybean line DP-305423-1 will require labelling as genetically modified even though it will not contain any novel protein or DNA.

Soybeans and their products are allergenic substances that must always be declared when present in food (refer clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations). Consequently, oil derived from soybean line DP-305423-1 will always need to be labelled as 'soybean oil', rather than the generic 'vegetable oil' as may be the case for some other oils. The requirement to label as 'genetically modified' is therefore also triggered in this particular case by Standard 2.4.1 – Edible Oils. Clause 3 of Standard 2.4.1 states that if the specific name of an oil is used, then the label must include a statement that describes the nature of any process that has been used to alter the fatty acid composition of the edible oil. In this case, oil derived from soybean line DP-305423-1 would require labelling as 'genetically modified'.

FSANZ has also considered whether imposing additional labelling requirements would be appropriate in this case. 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. Following a detailed consideration of how informative it would be to consumers to list changes in fatty acid profiles, FSANZ has concluded that any food derived from soybean line DP-305423-1 does not require additional labelling.

For previously approved soybean lines G94-1, G94-19 and G168 which, like soybean line DP-305423-1, contain high levels of oleic acid (see Table to Clause 2 in Standard 1.5.2) and are also the property of Pioneer Hi-Bred International Inc., the labelling statement is that the food has been genetically modified to contain high levels of oleic acid. The proposed labelling for soybean line DP-205423-1 is therefore different from that for these previously approved lines.

FSANZ acknowledges that the purpose of labelling foods is to provide meaningful nutritional information. Following public education campaigns consumers are now more likely to have a better understanding of the terms 'unsaturated' and 'saturated' with regard to fats, than to have an understanding of the differences between individual fatty acids. FSANZ now considers that it would be confusing for consumers if labelling addressed specific fatty acids and, given that the total concentration of unsaturated fatty acids in soybean line DP-305423-1 is essentially unaltered, considers that it is sufficient for the labelling to mention only that the product is genetically modified. Furthermore, the Applicant has advised that the previously approved soybean lines G94-1, G94-19 and G168 are no longer cultivated and therefore products derived from them are not available on the market.

This removes the likelihood of products from these lines and from soybean line DP-305423-1 occurring side-by-side for retail sale and appearing to lack consistency in labelling. Labelling to indicate minor changes in fatty acid compositions of heptadecanoic acid and heptadecanoic acid is not considered necessary based on their low abundance, lack of nutritional impact, and level of presence in other commonly consumed foods.

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*

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 amend Standard 1.5.2 to permit the sale and use of food derived from high oleic acid soybean line DP-305423-1, with or without specified conditions in the Table to clause 2 of 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 of soybean-containing food products, 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 of soybean-containing food products
    - food retailers

- Government:

    - enforcement agencies
    - National governments, in terms of trade and World Trade Organization (WTO) obligations.

Soybean line DP-305423-1 has been developed primarily for agricultural production overseas and, at this stage, the Applicant has no plans for cultivation of this variety in either Australia or New Zealand.

The cultivation of soybean 305423 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 by various New Zealand Government agencies including the Environmental Risk Management Authority (ERMA) and the Ministry of Agriculture and Forestry (MAF) before commercial release in either country could be permitted.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – Reject Application

Consumers: Possible restriction in the availability of imported soybean products to those products that do not contain soybean line DP-305423-1.

No impact on consumers wishing to avoid GM foods, as food from soybean line DP-305423-1 is not currently permitted in the food supply.

Potential increase in price of imported soybean foods due to requirement for segregation of soybean line DP-305423-1

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 soybean line DP-305423-1 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: Broader availability of imported soybean products as there would be no restriction on imported foods containing soybean line DP-305423-1.

Potentially, no increase in the prices of imported foods manufactured using comingled soybean products.

Appropriate labelling would allow consumers wishing to avoid GM soybean to do so.

Government: Benefit that if soybean line DP-305423-1 was detected in soybean imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of soybean line DP-305423-1 would ensure no conflict with WTO responsibilities.

This option could impact on monitoring resources, as certain foods derived from soybean line DP-305423-1 will be required to be labelled as genetically modified.

Industry: Importers of processed foods containing soybean derivatives would benefit as foods derived from soybean line DP-305423-1 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 soy products or imported foods manufactured using soybean derivatives.

Possible cost to food industry as some food ingredients derived from soybean line DP-305423-1 would be required to be labelled.

8.3 Comparison of Options

As food from high oleic acid soybean line DP-305423-1 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 soybean line DP-305423-1 by other countries could limit the availability of imported soy products in the Australian and New Zealand markets. In addition, Option 1 would result in the requirement for segregation of any products containing soybean 305423 from those containing approved soybean lines which would be likely to increase the costs of imported soy foods. Even though soybean 305423 will be grown under identity preservation, certain products may inadvertently be co-mingled with those from other soybean lines. This means that costs could be incurred if approval for soybean 305423 were not given.

Based on the conclusions of the safety assessments, the potential benefits of Option 2 outweigh the potential costs. A variation to Standard 1.5.2 giving approval to high oleic acid soybean line DP-305423-1 is therefore the preferred option.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

It is considered that this Application is a routine matter. Therefore, FSANZ has applied a basic communication strategy. This will involve advertising the availability of assessment reports for public comment in the national press and making reports available on the FSANZ website.

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 Council. If the approval of food derived from high oleic acid soybean line DP-305423-1 is not subject to review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the amendments to the Code in the national press and on the website.

10. Consultation

Public submissions are invited on this Assessment Report. Comments are specifically sought on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from high oleic acid soybean line DP-305423-1.

Comments on the proposed labelling requirements for food derived from soybean line DP-305423-1 are also invited.

10.1 World Trade Organization (WTO)

As members of the 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 draft variation to the Code would have a trade enabling effect as it would permit food derived from high oleic acid soybean DP 305423-1 to be imported into Australia and New Zealand and sold, where currently it is prohibited. For this reason it was determined there is no need to notify this Application as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Agreement on the Application of SPS Measures.

CONCLUSION

11. Conclusion and Preferred Option

Preferred Approach

Develop a food regulatory measure, to amend Standard 1.5.2 – Food produced using Gene Technology, to include food derived from high oleic acid soybean line DP-305423-1 in the Table to clause 2.

11.1 Reasons for Preferred Approach

The development of an amendment to the Code to give approval to the sale and use of food derived from high oleic acid soybean line DP-305423-1 in Australia and New Zealand is proposed on the basis of the available scientific evidence, for the following reasons:

- the safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce high oleic acid soybean line DP-305423-1

- seed from high oleic acid soybean line DP-305423-1 contains elevated levels of oleic acid and reduced levels of linoleic acid but is equivalent to other commercially available soybean varieties in terms of its safety for human consumption and nutritional adequacy

- labelling of certain foods derived from high oleic acid soybean line DP-305423-1 will be required in the ingredients list if novel DNA, novel protein or altered levels of oleic and linoleic acid are present in the final food

- 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, an amendment 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 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.

ATTACHMENTS

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

Attachment 1

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

Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

To commence: on gazettal

[1] ***Standard 1.5.2*** *of the Australia New Zealand Food Standards Code is varied by inserting in the* Table to clause 2 –

Food derived from high oleic acid soybean line DP-305423-1	