

5 November 2013

[20-13]

Call for submissions – Application A1087

Food derived from Insect-protected Soybean Line DAS-81419-2

FSANZ has assessed an Application made by Dow AgroSciences Australia Ltd seeking permission for food derived from soybean line DAS-81419-2, which is genetically modified to provide protection against several lepidopteran pests, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly 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 via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 17 December 2013

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Table of Contents

1. EXECUTIVE SUMMARY	2
2. INTRODUCTION	3
2.1 THE APPLICANTS	3
2.2 THE APPLICATION.....	3
2.3 THE CURRENT STANDARD.....	3
2.4 REASONS FOR ACCEPTING THE APPLICATION	3
2.5 PROCEDURE FOR ASSESSMENT	4
3. SUMMARY OF THE ASSESSMENT.....	4
3.1 RISK ASSESSMENT	4
3.2 RISK MANAGEMENT	4
3.2.1 <i>Cost/benefit analysis</i>	5
3.2.2 <i>Other measures</i>	6
3.2.3 <i>Relevant New Zealand standards</i>	6
3.2.4 <i>Any other relevant matters</i>	6
3.2.5 <i>Addressing FSANZ's objectives for standards-setting</i>	7
3.3. RISK COMMUNICATION.....	8
3.3.3 <i>World Trade Organization (WTO)</i>	9
4. DRAFT VARIATION.....	9
4.1.1 <i>Implementation</i>	9
5. REFERENCES	9
ATTACHMENT A – DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	10
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT.....	12

Supporting document

The following document, which informed the assessment of this Application, is available on the FSANZ website at <http://www.foodstandards.gov.au/code/applications/Pages/A1087-Food-derived-from-Insect-protected-Soybean-Line-DAS-81419-2.aspx>

SD1 Safety Assessment Report: Application A1087 – Food derived from Insect-protected Soybean Line DAS-81419-2

1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Dow AgroSciences Australia Ltd on 5 June 2013. The Applicants requested a variation 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 genetically modified (GM) soybean line DAS-81419-2, that is protected against several lepidopteran pests.

This Application is being assessed under the General Procedure.

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in section 18 of the FSANZ Act, is the protection of public health and safety. Accordingly, the safety assessment is a central part of considering an application.

The safety assessment of soybean line DAS-81419-2 is provided in Supporting Document 1. No potential public health and safety concerns have been identified. Based on the data provided in the present Application, and other available information, food derived from soybean line DAS-81419-2 is considered to be as safe for human consumption as food derived from conventional soybean cultivars.

FSANZ has prepared a draft variation to Standard 1.5.2 to include food derived from soybean line DAS-81419-2.

2. Introduction

2.1 The Applicants

Dow AgroSciences Australia Pty Ltd is a wholly owned subsidiary of the Dow Chemical Company and is a technology provider to the agricultural and food industries.

2.2 The Application

Application A1087 was submitted by Dow AgroSciences Australia Ltd on 5 June 2013. It sought approval for food derived from line DAS-81419-2 under Standard 1.5.2 – Food produced using Gene Technology.

Soybean line DAS-81419-2 is protected against several lepidopteran pests including soybean looper, velvetbean caterpillar, fall armyworm and tobacco budworm. This protection is conferred through the introduction of two insecticidal genes termed *cry1Ac(synpro)* and *cry1Fv*, both derived from the common soil bacterium *Bacillus thuringiensis*. The proteins expressed by the genes are identical in amino acid sequence to the same proteins expressed in WideStrike cotton considered by FSANZ in Application A518 (FSANZ, 2005).

In addition to the two *cry* genes, soybean 81419 contains a selectable marker gene (*pat*) from the bacterium *Streptomyces viridochromogenes*, which produces an enzyme (phosphinothricin acetyltransferase, PAT) that detoxifies the herbicide glufosinate ammonium. PAT functions as a selectable marker in the initial laboratory stages of plant cell selection and thus soybean 81419 is also tolerant to the herbicide glufosinate ammonium. However, it is not intended that this trait be used in commercial production of soybean 81419. The *pat* gene has been widely used for genetic modification of a number of crop species, including soybean.

2.3 The current Standard

Pre-market approval is necessary before food derived from any genetically modified (GM) line may enter the Australian and New Zealand food supply. Approval of GM foods under Standard 1.5.2 is contingent on completion of a comprehensive pre-market safety assessment. Foods that have been assessed and approved are listed in the Schedule to the Standard.

Standard 1.5.2 contains specific labelling provisions for approved GM foods. GM foods and ingredients (including food additives and processing aids from GM sources) must be identified on labels with the words 'genetically modified', if novel DNA and/or novel protein from an approved GM variety is present in the final food, or the food has altered characteristics. In the latter case the Standard also allows for additional labelling about the nature of the altered characteristics.

2.4 Reasons for accepting the Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

2.5 Procedure for assessment

The Application is being assessed under the General Procedure.

3. Summary of the assessment

3.1 Risk assessment

The safety assessment of soybean line DAS-81419-2 is provided in the supporting document (SD1) and included the following key elements:

- a characterisation of the transferred genes, their origin, function and stability in the soybean genome
- the changes at the level of DNA and protein in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes
- the potential for the newly expressed proteins to be either allergenic or toxic in humans.

The assessment of soybean line DAS-81419-2 was restricted to human food safety and nutritional issues. This assessment therefore does not address any risks to the environment that may occur as the result of growing GM plants used in food production, or any risks to animals that may consume feed derived from GM plants.

No potential public health and safety concerns have been identified.

On the basis of the data provided in the present Application, and other available information, food derived from soybean line DAS-81419-2 is considered to be as safe for human consumption as food derived from conventional soybean cultivars.

3.2 Risk management

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied 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
- whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Application
- any relevant New Zealand standards
- any other relevant matters.

Two regulatory options were considered: (1) prepare a draft variation to Standard 1.5.2 to include food derived from soybean line DAS-81419-12; or (2) reject the Application.

FSANZ has decided to prepare a draft variation to Standard 1.5.2 because the potential benefits of approving the variation outweigh the potential costs, and because no public health or safety concerns resulting from consumption of food derived from soybean line DAS-81419-2 have been raised.

3.2.1 Cost/benefit analysis

A consideration of the cost/benefit of the regulatory options is not intended to be an exhaustive, quantitative financial analysis of the options as 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.

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010 (reference 12065), provided an exemption from the need for the OBPR to be informed about GM food applications.

3.2.1.1 Option 1 – Develop a draft variation to Standard 1.5.2

Consumers: Broader availability of imported soybean products as there would be no restriction on imported foods containing soybean line DAS-81419-2.

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

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

Government: Benefit that if soybean line DAS-81419-2 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 DAS-81419-2 would ensure no conflict with WTO responsibilities.

In the case of approved GM foods, monitoring is required to ensure compliance with the 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 soybean line DAS-81419-2 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 soybean products or imported foods manufactured using soybean derivatives.

Possible cost to food industry as some food ingredients derived from soybean line DAS-81419-2 would be required to be labelled.

3.2.1.2 Option 2 – Reject application

Consumers: Possible restriction in the availability of imported soybean products to those products that do not contain soybean line DAS-81419-2.

No effect on consumers wishing to avoid GM foods, as food from soybean line DAS-81419-2 is not currently permitted in the food supply.

Potential increase in price of imported soybean foods due to requirement for segregation of soybean line DAS-81419-2.

Government: Potential effect if considered inconsistent with WTO obligations but this would be in terms of trade policy rather than in government revenue.

Industry: Possible restriction on imports of soybean food products if soybean line DAS-81419-2 were to be commercialised overseas.

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

As food from soybean line DAS-81419-2 has been found to be as safe as food from conventional cultivars of soybean, not preparing a draft variation would offer little benefit to consumers, as approval of soybean line DAS-81419-2 by other countries could limit the availability of imported soybean products in the Australian and New Zealand markets.

In addition, this option would result in the requirement for segregation of any products containing soybean line DAS-81419-2 from those containing approved soybean lines which would be likely to increase the costs of imported soybean-derived foods.

Based on the conclusions of the safety assessments, the potential benefits of approving the variation outweighed the potential costs.

3.2.2 Other measures

There were no measures that could achieve the same result other than an amendment to Standard 1.5.2.

3.2.3 Relevant New Zealand standards

Standard 1.5.2 applies in New Zealand.

3.2.4 Any other relevant matters

The Applicant has submitted applications for regulatory approval of DAS-81419-2 to a number of other countries, as listed in Table 1. To date, none has been finalised.

Table 1: List of countries to whom applications for food/feed regulatory approval of soybean line DAS-81419-2 have been submitted

Country	Agency	Type of approval sought
USA	Department of Agriculture	environment
	Environmental Protection Agency	food/feed/environment
	Food & Drug Administration	food/feed
Canada	Food Inspection Agency	feed
	Health Canada	food
Argentina	CONABIA	environment
	SENASA	food/feed
EU	European Food Safety Authority	food/feed

It is intended to submit applications to a number of other countries such as Mexico, Colombia, Korea, Japan, Taiwan, China, South Africa, and Philippines for food/feed regulatory approvals.

It is the Applicant's intention that soybean line DAS-81419-2 be commercially cultivated predominantly in North and South America. There is currently no intention to apply for approval to cultivate this line in either Australia or New Zealand. Cultivation in Australia or New Zealand would require prior independent assessment and approval by the Office of the Gene Technology Regulator in Australia and by the Environmental Protection Authority (EPA) in New Zealand.

3.2.5 Addressing FSANZ's objectives for standards-setting

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

3.2.5.1 Protection of public health and safety

Food derived from soybean line DAS-81419-2 has been assessed according to the safety assessment guidelines prepared by FSANZ (2007).

No public health and safety concerns were identified in this assessment. Based on the available evidence, including detailed studies provided by the Applicant, food derived from soybean line DAS-81419-2 is considered as safe and wholesome as food derived from other commercial soybean cultivars.

3.2.5.2 The provision of adequate information relating to food to enable consumers to make informed choices

GM foods are labelled to help consumers make an informed choice. In accordance with Standard 1.5.2, food derived from soybean line DAS-81419-2 would be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein or if it has altered characteristics. DAS-81419-2 does not have altered characteristics.

Soybean DAS-81419-2 is intended primarily for use as a broad-acre commodity (field soybean) to produce products derived from cracked soybeans, and is not intended for vegetable or garden purposes where food-grade products may include tofu, soybean sprouts, soy milk, and green soybean (e.g. edamame). This latter type of soybean generally has a different size, flavour and texture to field soybean. The main food product from field soybean is refined oil. Processing during production means novel protein and novel DNA are not likely to be present in the oil; in the absence of novel protein and novel DNA, refined oil from soybean line DAS-81419-2 would be exempt from labelling under paragraph 4(1)(c) of Standard 1.5.2. Other products such as protein concentrate, protein isolate and textured flour are likely to contain novel protein and/or novel DNA and if so, would require labelling.

3.2.5.3 The prevention of misleading or deceptive conduct

Detection methodology

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions was formed by the Implementation Subcommittee for Food Regulation (a subcommittee of the COAG Legislative and Governance Forum on Food Regulation¹ – the Forum) to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM applications.

The EAG has indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data to be provided. Using this information, any analytical laboratory would be able to develop a PCR-based detection method.

¹ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

This sequence information has been supplied by the Applicant for DAS-81419-2 to satisfy the requirement for detection methodology in the FSANZ Application Handbook (FSANZ, 2011).

3.2.5.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed in subsection 18(2):

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

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex General Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2004). Based on these principles, the risk analysis undertaken for soybean DAS-81419-2 used the best scientific evidence available. The Applicants submitted to FSANZ, a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the Applicants, other available resource material including published scientific literature and general technical information was used in the safety assessment.

- *The promotion of consistency between domestic and international food standards.*

This is not a consideration as there are no relevant international standards.

- *The desirability of an efficient and internationally competitive food industry.*

The inclusion of genetically modified foods in the food supply, providing there are no safety concerns, allows for innovation by developers and a widening of the technological base for the production of foods. Soybean line DAS-81419-2 is a new food crop designed to provide growers in a number of countries around the world with improved insect resistance management and an alternative to chemical insecticides.

- *The promotion of fair trading in food.*

The cost/benefit analysis in Section 3.2.1 lists a number of considerations that address fair trading with respect to soybean line DAS-81419-2.

Any written policy guidelines formulated by the Ministerial Council.

No specific policy guidelines have been developed since Standard 1.5.2 commenced.

3.3. Risk communication

FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options. FSANZ also publishes all applications on the FSANZ website.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received on this Call for Submissions.

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 Forum. If the Board's decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the website.

3.3.3 World Trade Organization (WTO)

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

There are no relevant international standards and amending the Code to permit food derived from insect-protected soybean line DAS-81419-2 is unlikely to have a significant effect on international trade as it would permit food derived from insect-protected soybean line DAS-81419-2 to be imported into Australia and New Zealand and sold, where currently sale is prohibited. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

4. Draft variation

The draft variation to Standard 1.5.2 is at Attachment A. A draft Explanatory Statement is at Attachment B.

4.1.1 Implementation

The variation would take effect on gazettal.

5. References

Codex (2004) *Principles for the risk analysis of foods derived from modern biotechnology*. Report No. CAC/GL 44-2003, Codex Alimentarius Commission, Rome.
http://www.codexalimentarius.net/web/standard_list.do?lang=en.

FSANZ (2005) *Application A518 - Food derived from Insect Protected cotton line MXB-13*. Report prepared by Food Standards Australia New Zealand.
<http://www.foodstandards.gov.au/code/applications/pages/applicationa518foodd2314.aspx>.

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.

FSANZ (2011) *Application handbook*. Prepared by Food Standards Australia New Zealand.
<http://www.foodstandards.gov.au/foodstandards/changingthecode/applicationshandbook.cfm>.

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1087 – Food derived from Insect-protected Soybean Line DAS-81419-2) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1087 – Food derived from Insect-protected Soybean Line DAS-81419-2) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

SCHEDULE

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

“

	7.15	Food derived from insect-protected soybean line DAS-81419-2	
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Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1087 which seeks permission for the sale and use of food derived from insect-protected soybean line DAS-81419-2. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

2. Purpose

Standard 1.5.2 of the Code currently sets out the permission and conditions for the sale and use of foods produced using gene technology (Schedule to the Standard). Food derived from soybean line DAS-81419-2 is not currently listed in the Schedule to Standard 1.5.2 and therefore is not permitted for sale or use in food. Therefore, FSANZ is proposing to vary Standard 1.5.2 by inserting into the Schedule a reference to food derived from soybean line DAS-81419-2.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1087 will include one round of public consultation following an assessment and the preparation of a draft variation.

A Regulation Impact Statement was not required because the use of food derived from soybean line DAS-81419-2, if approved, would be voluntary and would be likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

This item adds food derived from soybean line DAS-81419-2 to the Schedule to Standard 1.5.2.