12 March 2014
[04-14]

Approval Report – Application A1087

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

Food Standards Australia New Zealand (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.

On 5 November 2013, FSANZ sought submissions on a draft variation to Standard 1.5.2 and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation to the Standard on 6 March 2014. The COAG Legislative and Governance Forum on Food Regulation[1] (the Forum) was notified of FSANZ's decision on 11 March 2014.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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

Table of Contents

Supporting document

The following document used to prepare this Report is available on the FSANZ website at http://www.foodstandards.gov.au/code/applications/Pages/a1081foodderivedfrom5825.aspx

SD1 Safety Assessment (at Approval)

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Dow AgroSciences Australia Ltd on 5 June 2013. The Applicant 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.

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in s 18 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), is the protection of public health and safety. Accordingly, the safety assessment is central to 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.

A decision has been made to approve the draft variation to Standard 1.5.2 to include food derived from insect-protected soybean line DAS-81419-2 in the Schedule.

1. Introduction

1.1 The Applicant

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.

1.2 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, the Applicant states 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.

1.3 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 under the Standard, if 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 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.

1.4 Reasons for accepting the Application

The Application was accepted for assessment on the basis that:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- 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.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

1.6 Decision

The draft variation to Standard 1.5.2, as proposed following assessment, was approved without change. The variation takes effect on gazettal.

The approved draft variation to the Standard is at Attachment A. The explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

2. Summary of the findings

2.1 Summary of issues raised in submissions

2.1.1. General issues

The FSANZ safety assessment considers only the safety of GM food for human consumption. Two submissions raised general issues to do with public perception of GM food, and environmental issues, both of which are outside the scope of FSANZ's regulatory area. Issues to do with the growing of GM crops and any possible effects on the environment are considered in Australia by the Office of the Gene Technology Regulator, and in New Zealand by the Environmental Protection Authority.

Responses to seven general issues raised or implied, are provided in Table 1. Minor changes have been made to the SD1 to address typographical errors and clarity.

Table 1: Summary of general issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Concern with the safety of GM food	• Physicians & Scientists for Global Responsibility	The approach used by FSANZ to assess the safety of GM food is based on core principles developed almost 20 years ago and published as guidelines by the Codex Alimentarius Commission (Codex, 2003; Codex, 2004). Over time, the assessment protocol has been the subject of scientific scrutiny; however it has proved to be a robust approach for whole food safety assessments. It is widely adopted and implemented around the world. While philosophical opposition to the technology remains, consumers can be confident that GM foods assessed under the protocol and approved for food use are as safe as their conventional counterparts. Studies cited as evidence of safety concerns with certain GM foods have been examined by FSANZ and other scientific experts around the world. The studies have been subject to significant scientific criticism and generally are not supported. Responses to several recent publications are available on the FSANZ website (http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx).

Issue	Raised by	FSANZ Response (including any amendments to drafting)
The conduct of the FSANZ safety assessment	• Physicians & Scientists for Global Responsibility	FSANZ's safety assessment protocol is based on internationally recognised guidelines and technical advice (eg from the OECD), has been periodically reviewed by external experts either fully or in part, and has been refined in response to emerging scientific information. FSANZ monitors the publication of relevant studies and evaluates their importance to the safety assessment protocol. Reviews of key studies have been published on the FSANZ website ((http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx), including those published since the developed of the internationally agreed assessment protocol. FSANZ has outlined its approach to GM safety assessment in a Guidance Document (FSANZ, 2007) and specified the data requirements to support this approach in the FSANZ Application Handbook (FSANZ, 2011). A detailed description of the process used by FSANZ for the safety assessment of GM foods is available on the FSANZ website at http://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx In 2008, an external review of the FSANZ GM food safety assessment procedure was undertaken and identified a number of strengths (see FSANZ website at http://www.foodstandards.gov.au/consumer/gmfood/Pages/reviewofgeneticallym4394.aspx
Potential allergenicity of GM foods	• Physicians & Scientists for Global Responsibility	The occurrence of allergies in people eating Western diets is attributed to major allergens already in the food supply – milk, eggs and nuts, particularly peanuts. These commonly allergenic foods are not associated with GM commodities. There is no credible scientific basis to support the notion that food allergies are linked to the introduction of any GM crops or that allergens can arise spontaneously as a result of the genetic modification process (Goodman and Tetteh, 2011). Any novel proteins likely to be present in a GM food undergo individual assessment for both allergenicity and toxicity. The presence of soybean, whether from a GM or non-GM source, must be declared on a label so that soy-allergic individuals can avoid the food.
Horizontal gene transfer to gut bacteria and safety of ingesting recombinant DNA	• Physicians & Scientists for Global Responsibility	There is no indication that novel genetic material in food will have an impact on human health. This issue has been considered in detail by FSANZ and a summary is available on the FSANZ website - http://www.foodstandards.gov.au/consumer/gmfood/recombinantdna/Pages/default.aspx
The safety of ingesting transgenes	• Physicians & Scientists for Global Responsibility	DNA is a natural component of the human diet, being present to varying degrees in many plant- and animal- derived foods, especially those that have undergone minimal processing. There is no difference in terms of risk between small fragments of recombinant DNA and the DNA already present in our diet.

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Lack of consideration of feeding studies in the safety assessment	• Physicians & Scientists for Global Responsibility • Vicki Martin	In 2007, FSANZ convened a workshop to formally examine the usefulness of animal feeding studies to support the safety assessment of GM foods (http://www.foodstandards.gov.au/consumer/gmfood/Pages/roleofanimalfeedings3717.aspx). The conclusion was that such studies do not contribute meaningful information on the long-term safety of a GM food, with the possible exception of a food in which the modification introduced a desired nutritional change. In these limited cases, the altered nutritional profile of the food may lend itself to investigation in animal diets, or in human volunteers. However, the majority of GM crops with agronomic traits have the same nutritional profile as conventional foods. While the European Food Safety Authority (EFSA) did not advocate the inclusion of a 90-day feeding study in those cases where molecular, compositional, phenotypic and agronomic analyses demonstrated equivalence of the GM food to its non-GM counterpart (EFSA, 2008; EFSA, 2011) the European Commission (EC) decided, in December 2013, to require a 90-day study with each GM food application, pending the outcome of a European Union research project on that issue by the end of 2015. Depending on results from the 90-day study or other available nutritional and toxicological studies, a 2-year study in rats may also be requested by the EC on a case-by-case basis (EFSA, 2013). FSANZ, along with most experts in toxicology, considers that animal feeding studies are unlikely to provide additional useful information in circumstances where the compositional analysis of whole food reveals no significant differences. There are also concerns about the unethical use of animals for feeding studies in the absence of any clearly identified compositional differences (Bartholomaeus *et al*., 2013; Rigaud, 2008). Recent publications (Séralini *et al*, Carman *et al*)[2] have claimed to show evidence of harm in animals fed GM food. However, assessment of these studies by FSANZ and others indicates these claims are not supported by the data presented by the researchers. In late November 2013,the Séralini *et al* paper was retracted by the publishing journal on the grounds of poor study design (http://www.prnewswire.co.uk/news-releases/elsevier-announces-article-retraction-from-journal-food-and-chemical-toxicology-233754961.html). FSANZ has published a scientific appraisal of a number of studies claiming to show adverse effects in animals fed GM feed (see http://www.foodstandards.gov.au/consumer/gmfood/Pages/Response-to-Dr-Carman's-study.aspx ; http://www.foodstandards.gov.au/consumer/gmfood/seralini/Pages/default.aspx)

[2] Séralini, G.-E.; Clair, E.; Mesnage, R.; Gress, S.; Defarge, N.; Malatesta, M.; Hennequin, D.; Spiroux de Vendemois, J. (2012). Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically-modified maize. *Food and Chemical Toxicology* 50: 4221 – 4231.
Carman, J.A., Vlieger, H.R., Ver Steeg, L.J., Sneller, V.E., Robinson, G.W., Clinch-Jones, C.A., Haynes, J.I. and Edwards, J.W. (2013) A long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet. *Journal of Organic Systems* 8(1):38-54.

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Lack of independent research	• Physicians & Scientists for Global Responsibility	FSANZ requires the developer of any new GM food to demonstrate its safety. The data required are specified and must be generated according to quality assurance guidelines that are based on internationally accepted protocols and be able to withstand external scrutiny. FSANZ independently assesses the data provided by the developer to reach a conclusion about the safety of the food. FSANZ complements data generated by the developer with information from the scientific literature, other applications, other government agencies and the public. FSANZ has addressed this issue in a Q & A fact sheet on the website at http://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx

2.1.2 Specific issues raised

2.1.2.1 Presence of Cry protein in blood

The Physicians & Scientists for Global Responsibility cite a paper by Aris & Leblanc (2011)[3] in which it was claimed that Cry1Ab protein was found in the blood of pregnant and non-pregnant women and in the umbilical cord blood from babies.

Response

FSANZ has previously reviewed and prepared a public response to this paper (available at http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx). Apart from identifying flaws in the experimental approach used by the researchers, the response noted that there were no safety implications linked to the presence of Cry1Ab in the human body, and that there were no abnormalities in either the subjects or, in the case of those who were pregnant at the time of the study, the subsequent process of birth or the health of the mothers and babies postpartum.

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

The assessment of soybean line DAS-81419-2 was restricted to food safety and nutritional issues.

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[3] Aris, A. and Leblanc, S. (2011) Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada. *Reproductive Toxicology* 31(4):528-533.

Any risks related to the release into the environment of GM plants used in food production, or risks to animals consuming feed derived from GM plants have not been addressed in this assessment.

The Applicant for A1087 met all of the data requirements stipulated in the *Application Handbook* (FSANZ, 2011) for the safety assessment of GM food and, after assessing these data, FSANZ is satisfied that sufficient evidence has been provided to demonstrate the safety of the food.

Based on the scientific 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 lucerne cultivars.

2.3 Risk management

2.3.1 Labelling

In accordance with the labelling provisions in Standard 1.5.2, food derived from soybean line DAS-81419-2 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein, or has altered characteristics. Food from line DAS-81419-2 does not have altered characteristics.

Soybean line 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.

2.3.2 Detection methodology

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee[4] 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 is sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the Applicant for DAS-81419-2 to satisfy the requirement for detection methodology in the FSANZ *Application Handbook* (FSANZ, 2011).

2.4 Risk communication

Consultation is a key part of FSANZ's Standards development process.

The process by which FSANZ considers Standards matters is open, accountable, consultative and transparent.

[4] Now known as the Implementation Subcommittee for Food Regulation

Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

Public submissions were invited on a draft variation which was released for public comment between 5 November and 17 December 2013. The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media tools and the publication, Food Standards News. Subscribers and interested parties were also notified.

Four submissions were received, of which two objected to the proposed variation.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on an application or proposal is considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

Documents relating to Application A1087, including submissions received, are available on the FSANZ website.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Cost benefit analysis

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010, granted a standing exemption from the need of the OBPR to assess if a Regulatory Impact Statement is required for the approval of additional genetically modified foods (reference 12065). This standing exemption was provided as such changes are considered as minor, machinery and deregulatory in nature. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ undertook a cost benefit analysis (see below). The analysis concluded that the costs arising from a food regulatory measure developed or varied as a result of the application would not 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.
A consideration of the cost/benefit of approving the draft variation is not intended to be an exhaustive, quantitative dollar analysis of the options and, in fact, most of the impacts that are considered cannot be assigned a dollar value. Rather, the analysis seeks to highlight the qualitative impacts of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

The points below list the effect that approving the draft would be expected to have on various sectors. It is noted that the cost/benefit analysis is speculative and is based on the assumption that soybean line DAS-81419-2 will be approved for growing in other countries (see section 2.5.1.4 below).

Consumers: Broader availability of imported soybean products as, if DAS-81419-2 is approved for commercial growing, there would be no restriction on imported foods containing this line.

For those soybean line DAS-81419-2 products containing novel DNA or novel protein, appropriate labelling would allow consumers wishing to avoid these products to do so.
If soybean DAS-81419-2 is approved for commercial growing in overseas countries, it can be used in the manufacture of products using co-mingled soybean. This means that there would be no cost involved in having to

exclude line DAS-81419-2 from co-mingling and hence that there would be no consequential need to increase the prices of imported foods that are manufactured using comingled soybean products.

Government: Benefit that if soybean line DAS-81419-2 was detected in food 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 81419-2 would ensure no conflict with WTO responsibilities if the line is approved for commercial growing in overseas countries.

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 food ingredients derived from soybean line DAS-81419-2 would be required to be labelled if they contain novel DNA or novel protein.

The segregation of raw agricultural commodities of DAS-81419-2, as for any GM crop, will be driven by industry, based on market preferences. Implicit in this will be a due regard to the costs of maintaining various levels of purity.

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.

Also, not preparing a draft variation is likely to be inconsistent with Australia's and New Zealand's WTO obligations if soybean DAS-81419-2 is approved for commercial growing in other countries (see below).

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

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

Standard 1.5.2 applies in New Zealand.

2.5.1.4 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 2. To date, none has been finalised.

Table 2: 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
Switzerland	Federal Office of Public Health	food/feed
South Africa	Department of Agriculture, Forestry and Fisheries	food/feed
Brazil	National Technical Commission on Biosafety (CTNBio)	food/feed/environment

The Applicant intends to submit applications to a number of other countries such as Mexico, Colombia, Korea (early 2014), Japan (early 2014), 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.

2.5.2 Subsection 18(1)

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

2.5.2.1 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.

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

In accordance with existing labelling provisions, food derived from soybean line DAS-81419-2 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see Section 2.3.1).

2.5.2.3 The prevention of misleading or deceptive conduct

The requirement for detection methodology (see Section 2.3.2) is designed to address this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **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 line DAS-81419-2 used the best scientific evidence available. The Applicant submitted to FSANZ, a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the Applicant, 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, where there are no safety concerns, generally allows for innovation by developers and a widening of the technological base for the production of foods.

- **The promotion of fair trading in food**

The cost/benefit analysis in Section 2.5.1.1 lists a number of considerations that address fair trading with respect to food derived from 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. References

Bartholomaeus, A., Parrott, W., Bondy, G. and Walker, K. (2013) The use of whole food animal studies in the safety assessment of genetically modified crops: Limitations and recommendations. *Critical Reviews in Toxicology* 43(S2):1-24.

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.

EFSA. (2008) Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials. *Food and Chemical Toxicology* 46:S1-S70, doi:10.1016/j.fct.2008.02.008.

EFSA. (2011) Guidance for risk assessment of food and feed from genetically modified plants. *EFSA Journal 2011* 9(5):2150.

EFSA. (2013) Consideration of the applicability of OECD TG 453 to whole food/feed testing. *EFSA Journal 2013* 11(7):3347 (18 pp).

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.

Goodman, R.E. and Tetteh, A.O. (2011) Suggested improvements for the allergenicity assessment of genetically modified plants used in foods. *Current Allergy and Asthma Reports* 11:317-324.

Rigaud, N. (2008) *Biotechnology: ethical and social debates*. OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda". http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/40926844.pdf.

Attachments

A. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

Attachment A – Approved 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

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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 a Standard 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	

"

Attachment B – 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 the variation to Standard 1.5.2.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation[5], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act 2003*.

2. Purpose

As it is not listed in the Schedule to Standard 1.5.2, food derived from soybean line DAS-81419-2 is not currently permitted for sale or use in food. This variation permits the sale, or use in food, of food derived from soybean line DAS-81419-2.

3. Documents incorporated by reference

This variation does 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 included one round of public consultation following an assessment and the preparation of a draft variation to the Standard and associated report. Submissions were called for on 5 November 2013 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Standard 1.5.2 is 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.

[5] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

6. Variation

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