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[2-14]

Approval Report – Application A1085

Food derived from Reduced Lignin Lucerne Line KK179

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Monsanto Australia Ltd seeking permission for food derived from lucerne line KK179, which is genetically modified to have reduced lignin levels.

On 8 October 2013, FSANZ sought submissions on a draft variation to Standard 1.5.2 and published an associated report. FSANZ received 11 submissions.

FSANZ approved the draft variation to the Standard on 12 February 2014. The COAG Legislative and Governance Forum on Food Regulation¹ (the Forum) was notified of FSANZ's decision on 20 February 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

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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

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Ltd on 10 April 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) lucerne line KK179 that has reduced lignin levels. The genetic modification is intended to benefit growers of lucerne forage for animal feed by providing a line with greater harvest flexibility that allows later harvest without appreciable loss of forage quality. It is not intended that KK179 enter the food supply. However, a food approval is sought in case this inadvertently occurs.

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 lucerne line KK179 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 lucerne line KK179 is considered to be as safe for human consumption as food derived from conventional lucerne cultivars.

A decision has been made to approve the draft variation to Standard 1.5.2 to include food derived from reduced lignin lucerne line KK179 in the Schedule.

1. Introduction

1.1 The Applicant

Monsanto Australia Ltd is a technology provider to the agricultural and food industries.

1.2 The Application

Application A1085 was submitted by Monsanto Australia Ltd on 10 April 2013. It sought approval for food derived from lucerne line KK179 under Standard 1.5.2 – Food produced using Gene Technology.

Lucerne line KK179 has reduced lignin content. Lignin is a non-carbohydrate phenolic polymer deposited in plant cell walls, particularly in the vascular tissue, and is a contributor to the quality of forage eaten by grazing animals.

The reduced level of lignin in lucerne KK179 has been achieved using RNA interference (RNAi), in which a fragment of a lucerne gene is introduced to suppress the expression of one of the genes involved in lignin biosynthesis. The Applicant claims this modification will provide growers with greater flexibility at harvest time, enabling the crop to be harvested at a later stage without appreciable loss of forage quality.

The Applicant states it is not intended that KK179 enter the food supply. However, a food approval is sought in case this inadvertently occurs.

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. Of the 11 submissions received, some raised issues that are outside the scope of FSANZ's regulatory area, e.g. public perception of GM food; the impact of GM crops on the organic industry; maintaining a GM-free trade status, opinions about biotechnology developers; feeding animals GM feed; and environmental issues. 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 nine general safety issues raised or implied, are provided in Table 1.

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	<ul style="list-style-type: none">Physicians & Scientists for Global ResponsibilityOrganic Dairy Farmers Australia	<p>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 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.</p> <p>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).</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>The conduct of the FSANZ safety assessment</p>	<ul style="list-style-type: none"> • Physicians & Scientists for Global Responsibility • Organic Dairy Farmers Australia • Sonja Caraian • Stefan Tupper 	<p>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.</p> <p>FSANZ has outlined its approach to GM safety assessment in a Guidance Document (FSANZ, 2007b) and specified the data requirements to support this approach in the FSANZ Application Handbook (FSANZ, 2011).</p> <p>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</p> <p>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)</p>
<p>Potential allergenicity of GM foods</p>	<ul style="list-style-type: none"> • Physicians & Scientists for Global Responsibility 	<p>The occurrence of allergies in people eating Western diets is attributed to major allergens already in the food supply – milk, eggs and tree 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).</p> <p>Any novel proteins likely to be present in a GM food undergo individual assessment for both allergenicity and toxicity.</p>
<p>Horizontal gene transfer to gut bacteria and safety of ingesting recombinant DNA</p>	<ul style="list-style-type: none"> • Physicians & Scientists for Global Responsibility 	<p>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</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Labelling of GM food	<ul style="list-style-type: none"> • Physicians & Scientists for Global Responsibility • Organic Dairy Farmers Australia 	<p>Only those GM foods assessed by FSANZ as safe are approved for sale. The labelling of approved GM foods is therefore not for safety reasons.</p> <p>The labelling requirements for approved GM foods to be labelled as 'genetically modified' if novel DNA or novel protein is present in the final food allow consumers to avoid those foods in which GM material (novel DNA or novel protein) is present or where the food has characteristics (e.g. an altered fatty acid profile) that are not normally associated with a non-GM counterpart. This labelling approach also allows practical enforcement since it does not require labelling of those GM-derived foods, such as highly refined oils, that are analytically indistinguishable from non-GM-derived foods.</p> <p>Labelling is also not required for an approved GM food when it is unintentionally present in a quantity of no more than 1% in the final food. This threshold is practical and recognises that a small amount of cross-over may occur between consignments of GM and non-GM commodities.</p> <p>Labelling requirements are stated in Standard 1.5.2 (http://www.comlaw.gov.au/Series/F2008B00628).</p> <p>Various other documents are available on the FSANZ website explaining the labelling requirements for GM foods. Links to these documents are provided below.</p> <p>Labelling of GM Foods http://www.foodstandards.gov.au/consumer/gmfood/labelling/pages/default.aspx</p> <p>GM Labelling Review Report http://www.foodstandards.gov.au/newsroom/publications/gm_labellingreviewrep2460.cfm</p>
Concern with possible chemical residues	<ul style="list-style-type: none"> • Organic Dairy Farmers Australia • Organic Federation of Australia • Australian Organic Ltd • NASAA Certified Organic 	<p>The use of agricultural and veterinary chemicals is subject to strict government regulation in most trading countries. In Australia and New Zealand, residues of agricultural and veterinary chemicals are prohibited in food (both GM and non-GM) unless they comply with specific limits referred to as Maximum Residue Limits (MRLs). The setting of MRLs ensures that residues of agricultural and veterinary chemicals are kept as low as possible and consistent with the approved use of chemical products to control pests and diseases of plants and animals. For further details see the FSANZ website at http://www.foodstandards.gov.au/consumer/chemicals/maxresidue/Pages/default.aspx</p> <p>MRLs are entered into the Schedule in Standard 1.4.2 Maximum Residue Limits in the Code, and apply to the listed food commodity, regardless of whether it is a conventional or GM crop.</p> <p>The pattern of use and resultant residues are taken into account in establishing the MRL.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>Lack of consideration of feeding studies in the safety assessment</p>	<ul style="list-style-type: none"> Physicians & Scientists for Global Responsibility Sonja Caraian 	<p>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.</p> <p>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).</p> <p>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 <i>et al.</i>, 2013; Rigaud, 2008).</p> <p>Recent publications (Séralini <i>et al</i>, Carman <i>et al</i>)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 <i>et al</i> 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).</p> <p>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)</p>

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., Vlioger, 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	<ul style="list-style-type: none"> • Hugh Halliday 	<p>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.</p> <p>FSANZ complements data generated by the developer with information from the scientific literature, other applications, other government agencies and the public.</p> <p>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</p>
The safety of food from animals fed GM feed	<ul style="list-style-type: none"> • Physicians & Scientists for Global Responsibility • Organic Dairy Farmers Australia • Organic Federation of Australia • Australian Organic Ltd • NASAA Certified Organic 	<p>Scientific evidence published so far, including by the OECD (OECD, 2003) and EFSA (EFSA, 2010), indicates that feeding GM plant material to animals does not affect the nutritional value or safety of the meat, milk and eggs derived from those animals. Minute traces of recombinant DNA fragments have occasionally been detected in animal tissues but there is no basis to suppose that these pose a hazard. This is because DNA is a natural component of the human diet, it being present to varying degrees in many plant and animal derived foods. There is no difference in terms of risk between small fragments of recombinant DNA and the DNA already present in our diet.</p> <p>In the case of GM plants intended primarily for use as animal feed, it is now standard practice for these to also undergo food safety assessment and approval for human food use. This recognises it may be impossible to prevent inadvertent co-mingling of plant material during cultivation, transport and storage, and so ensures their use as feed will not pose indirect risks to humans.</p>

2.1.2 Specific issues raised

2.1.2.1 Issue 1 – Breeding of KK179 with other GM lucerne lines

Organic Dairy Farmers Australia (ODFA), Organic Federation of Australia, NASAA Certified Organic, Australian Organic Ltd and Physicians & Scientists for Global Responsibility were concerned that, while the Applicant has stated line KK179 will be cross-bred with two other approved GM lucerne lines (J101 and J163 – Application A575), there has been no assessment of the safety of the resulting stacked events.

Response

No separate approval is necessary for foods derived from a stacked GM line that is the result of traditional breeding between a number of approved GM parent lines. See the definition of a 'line' in Standard 1.5.2.

The safety of the trait(s) introduced into each approved parental line is thoroughly assessed. The potential food risks associated with stacked GM plant lines which are products of traditional breeding of approved GM parental lines can be regarded as fundamentally no different from those occurring with any other conventionally bred plant. In the case of KK179, there is no scientific reason for any interaction between the herbicide-tolerance trait (of lines J101 and J163) and the reduced-lignin trait (of line KK179).

Information on stacked events can be found on the FSANZ website at <http://www.foodstandards.gov.au/consumer/gmfood/stackedgene/Pages/default.aspx>

2.1.2.2 Issue 2 – Labelling of products derived from KK179

In their submission, the Victorian Departments of Environment & Primary Industries and Health questioned the basis of the following statement made in the assessment summary:

FSANZ notes it is not intended that KK179 enter the food supply. However should it enter, food derived from reduced lignin Lucerne line KK179 would be required to be labelled as genetically modified if novel DNA or novel protein is present in the final food.

In their view, labelling may not be required because it would be more likely for food derived from Lucerne line KK179 to be ‘unintentionally present in a quantity of not more than 10 g/kg’.

Response

FSANZ agrees that if this GM line is unintentionally present in food at a level under the threshold of 10 g/kg (1 %) per ingredient, the food would be exempt from labelling in accordance with paragraph 4(1)(f) of Standard 1.5.2.

The requirement for GM labelling would be triggered only where lucerne line KK179 is used intentionally as an ingredient and novel DNA is present in the final food. Although as previously indicated, KK179 is not intended to enter the food supply.

2.1.2.3 Issue 3 – Cost/benefit

ODFA believed that in weighing the potential costs of approving food derived from lucerne line KK179 against the direct/indirect benefits, FSANZ failed to have regard to a number of relevant factors. Those factors, not already addressed in Sections 2.1.1 and 2.1.2, include:

- increased costs to a) organic and non-GM farmers, b) organic/GM free products because of increased segregation costs
- restriction in the availability of imported alfalfa products that do not contain KK179
- potential disruption to trade with trading parties that have not approved KK179
- negative impact on Australia’s ‘clean and green’ reputation
- Australian exporters could be negatively impacted if trade partners wish to avoid GM
- ODFA does not agree with the assumption that not approving food from KK179 would conflict with Australia’s WTO responsibilities
- ODFA considers a WTO challenge would actually have a positive impact on the food industry.

Response

FSANZ acknowledges the predominantly economic concerns expressed by stakeholders involved in the organic industry in Australia.

Several of the issues raised appear to relate to the cultivation of GM lucerne in Australia and/or New Zealand, such as potential disruption of trade with trading partners that have not approved lucerne line KK179, impact on the 'clean and green' reputation and impact on Australian exporters. FSANZ notes that the current application is for the importation of food derived from this line, should the line be approved for commercial cultivation overseas, and not for the cultivation in Australia or New Zealand of lucerne line KK179. Any decision on whether cultivation of line KK179 could be licensed in Australia or New Zealand would be the responsibility of other agencies (see Section 2.1.1).

FSANZ notes that the requirement of Standard 1.5.2 for pre-market approval of GM foods, including foods from lucerne line KK179, leads to controls on the supply of approved and non-approved GM foods, with associated compliance and certification costs. The costs of segregation of the raw agricultural commodity of lucerne line KK179 would be comparable to those of any other GM commodity and are based on decisions made by industry based on market preferences.

However, FSANZ does not agree with the argument that the approval of food derived from lucerne KK179 in Australia and New Zealand would, of itself, be a major factor in any adverse effects on international or domestic trade in lucerne products. Rather, FSANZ considers that approval of lucerne KK179 is appropriate for the following reasons:

- the pre-market safety assessment conducted by FSANZ found no public health and safety concerns associated with food derived from KK179.
- rejection of this Application without a risk assessment supporting this decision could expose Australia and New Zealand to challenges in the WTO or potentially compromise other legitimate trade agreements.
- obtaining regulatory approval in a number of importing countries before commercialisation is appropriate and necessary to ensure no disruption to international trade.
- food derived from two other GM lucerne lines has previously been approved in Australia and New Zealand (FSANZ, 2007a). FSANZ is not aware of any adverse economic impacts for the industry as a result of these approvals.

2.2 Safety assessment

The safety assessment of lucerne line KK179 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 lucerne genome
- the changes at the level of DNA and RNA in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes

The assessment of lucerne line KK179 was restricted to food safety and nutritional issues. 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 A1085 met all of the data requirements stipulated in the *Application Handbook* (FSANZ, 2011) for the safety assessment of GM food and, upon assessment of 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 lucerne line KK179 is considered to be as safe for human consumption as food derived from conventional lucerne cultivars.

2.3 Risk management

2.3.1 Labelling

Approved GM food is required to be labelled as 'genetically modified' if novel DNA or novel protein is present in the final food, unless the approved GM food is unintentionally present in a quantity of no more than 10 g/kg (1 %) per ingredient.

As noted in section 1.2, lucerne line KK179 is not intended to enter the food supply. If lucerne line KK179 was unintentionally present as a result of co-mingling, it is unlikely that the threshold for unintended presence would be exceeded and labelling triggered. It is further noted that, because the genetic modification involves RNAi, using sequences from an endogenous gene, it is unlikely that there will be novel protein present in any KK179 food products.

However, if food applications for lucerne line KK179 are developed in the future and it is used as an ingredient in food, then labelling requirements would apply in accordance with Standard 1.5.2.

Standard 1.5.2 also contains a 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*. In developing the GM food labelling standard, it was recognised there may be instances where additional labelling would be appropriate, for example where a property or characteristic of the food means that it is no longer equivalent to an existing counterpart food (Proposal P97).

Lucerne line KK179 has a reduced level of lignin compared with a non-GM comparator. While this reduction in lignin content changes the agronomic characteristics of the crop, the lignin level is within the normal range of variation found in non-GM lucerne and is therefore not considered to be of nutritional significance for humans. It is noted that the intent of the genetic modification was not to alter the nutritional profile *per se* but rather to alter an agronomic trait. Line KK179 is therefore not considered to have *significant composition or nutritional parameters* for the purposes of labelling GM foods.

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-Committee³ 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 KK179 to satisfy the requirement for detection methodology in the FSANZ *Application Handbook* (FSANZ, 2011).

³ Now known as the Implementation Subcommittee for Food Regulation

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. 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 8 October and 19 November 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.

Eleven submissions were received, of which one did not object to the proposed variation and two supported the proposed variation. Three submissions objecting to the approval of food derived from KK179 were received from private, independent submitters and five submissions (four of which were similarly worded submissions from the organic industry) objecting to the approval were received from non-government organisations.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments may be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

Documents relating to Application A1085, 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.

The costs that would arise 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 should be noted it is not intended that lucerne line KK179 be for human consumption as its purpose is for use in animal feed, primarily in northern America. The Applicant has stated that the Monsanto/Forage Genetics International (FGI) Technology Use Agreement with growers for this product would strictly prohibit the commercial sale of KK179 alfalfa seed for food uses. Further, the production of KK179 alfalfa seed would only be permitted through strict licensing agreements between growers and Monsanto/FGI, which require that all seed be returned to Monsanto/FGI. The following options are therefore relevant in the event of inadvertent entry of food from line KK179 into the Australian/New Zealand food supply, following approval for commercial growing overseas. As the Applicant has indicated there is no current intention of growing KK179 in Australia or New Zealand and fresh sprouts are not imported, the most likely route of inadvertent entry would be via imported co-mingled seed for sowing or sprouting.

In this case, since the seed would be a living genetically modified organism (GMO) it would, in the first instance, be subject to the regulations governing the release of a GMO into the environment and would therefore come under the jurisdiction of the Office of the Gene Technology Regulator in Australia and the Environmental Protection Authority in New Zealand. Any intentional importation and/or growing of viable GM lucerne in New Zealand would require an approval under the *Hazardous Substances and New Organisms Act 1996*. Relevant information on the importation of lucerne seed is available on the NZ Ministry for Primary Industries website (http://www.biosecurity.govt.nz/related/related_faqs/ihs/search?page=2&expand=2475).

Consumers: Broader availability of imported lucerne products as, if line KK179 were to be approved for commercial growing overseas, there would be no restriction on imported foods containing or comprising this line, providing those products did not breach regulatory requirements concerning environmental release.

The safety assessment found that there would be no impact on public health and safety if KK179 were introduced into the food supply.

Government: Benefit that if lucerne line KK179 was detected in lucerne imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds. Approval of lucerne line KK179 would ensure no conflict with WTO responsibilities if the line is approved for commercial growing in other countries.

Industry: Importers of processed foods containing lucerne derivatives would benefit as foods derived from lucerne line KK179 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 lucerne products or imported foods manufactured using lucerne derivatives.

The segregation of raw agricultural commodity of KK179, 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 lucerne line KK179 has been found to be as safe as food from conventional cultivars of lucerne, not preparing a draft variation would offer little benefit to consumers, as approval of lucerne line KK179 by other countries could limit the availability of imported lucerne products in the Australian and New Zealand markets.

In addition, this option would result in the requirement for segregation of any products containing lucerne line KK179 from those containing approved lucerne lines which would be likely to increase the costs of imported lucerne-derived products.

Also, not preparing a draft variation is likely to be inconsistent with Australia’s and New Zealand’s WTO obligations if lucerne KK179 is approved for commercial growing in other countries.

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 a food and feed safety and nutritional assessment summary for KK179 to the United States Food and Drug Administration and has also requested a Determination of Nonregulated Status for KK179, including all progenies derived from crosses between KK179 and other lucerne, from the Animal and Plant Health Inspection Service of the US Department of Agriculture.

The Applicant has submitted applications for regulatory approval of KK179 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 approval of lucerne line KK179 have been submitted

Country	Agency	Type of approval sought
Canada	Food Inspection Agency	feed
	Health Canada	food
Japan	Ministry of Health, Labor, and Welfare	food
	Ministry of Agriculture, Forestry and Fisheries	feed
Korea	Ministry of Food and Drug Safety (Formerly Korea Food and Drug Administration)	food
	Rural Development Administration	feed
Singapore	Agri-Food and Veterinary Authority	food/feed

Regulatory submissions will be made to countries that import significant lucerne or food and feed products derived from countries where KK179 lucerne will be grown, including, but not limited to Ministry of Agriculture, People’s Republic of China.

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 lucerne line KK179 has been assessed according to the safety assessment guidelines prepared by FSANZ (2007b).

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 lucerne line KK179 is considered as safe and wholesome as food derived from other commercial lucerne 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 lucerne line KK179 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 lucerne line KK179 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. Lucerne line KK179 is intended for livestock feed only. Food approval was sought to ensure compliance with the Code in case inadvertent entry into the food supply occurs.

- **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 lucerne line KK179.

- **Any written policy guidelines formulated by the Ministerial Council**

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

3. References

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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 A1085 – Food derived from Reduced Lignin Lucerne Line KK179) 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 (A1085 – Food derived from Reduced Lignin Lucerne Line KK179) 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

“

	4.2	Food derived from reduced lignin lucerne line KK179	
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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 A1085 which seeks permission for the sale and use of food derived from reduced lignin lucerne line KK179. 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 Regulation⁴, 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 sunseting under the *Legislative Instruments Act 2003*.

2. Purpose

As it is not listed in the Schedule to Standard 1.5.2, food derived from lucerne line KK179 is not currently permitted for sale or use in food. This variation permits the sale, or use in food, of food derived from lucerne line KK179.

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 A1085 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 8 October 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.

⁴ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

6. Variation

This item adds food derived from lucerne line KK179 to the Schedule to Standard 1.5.2.