

12 March 2014
[04-14]

Approval Report – Application A1089

Food derived from Herbicide-tolerant Canola Line DP-073496-4

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Pioneer Hi-Bred Australia Pty Ltd seeking permission for food derived from canola line DP-073496-4, which is genetically modified for tolerance to the herbicide glyphosate.

On 13 December 2013, FSANZ sought submissions on a draft variation to Standard 1.5.2 and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation to the Standard on 6 March 2014. The COAG Legislative and Governance Forum on Food Regulation¹ (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

EXECUTIVE SUMMARY	2
1. INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD	3
1.4 REASONS FOR ACCEPTING THE APPLICATION	3
1.5 PROCEDURE FOR ASSESSMENT	3
1.6 DECISION	4
2. SUMMARY OF THE FINDINGS	4
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	4
2.2 SAFETY ASSESSMENT	8
2.3 RISK MANAGEMENT	9
2.3.1 <i>Labelling</i>	9
2.3.2 <i>Detection methodology</i>	9
2.4 RISK COMMUNICATION	10
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS	10
2.5.1 <i>Section 29</i>	10
2.5.1.1 <i>Cost benefit analysis</i>	10
2.5.1.2 <i>Other measures</i>	11
2.5.1.3 <i>Any relevant New Zealand standards</i>	12
2.5.1.4 <i>Any other relevant matters</i>	12
2.5.2 <i>Subsection 18(1)</i>	12
2.5.2.1 <i>Protection of public health and safety</i>	12
2.5.2.2 <i>The provision of adequate information relating to food to enable consumers to make informed choices</i>	13
2.5.2.3 <i>The prevention of misleading or deceptive conduct</i>	13
3. REFERENCES	14
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE	15
ATTACHMENT B – EXPLANATORY STATEMENT	17

Supporting documents

The following document is available on the FSANZ website at
<http://www.foodstandards.gov.au/code/applications/Pages/A1089.aspx>

SD1: Safety Assessment Report: Application A1089 – Food derived from Herbicide-tolerant Canola line DP-073496-4 (at Approval)

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Pioneer Hi-Bred Australia Pty Ltd on 7 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) canola line DP-073496-4, tolerant to the herbicide glyphosate. The genetic modification is intended to benefit canola growers by providing alternative strategies for managing competition from weeds.

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 canola line DP-073496-4 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 herbicide-tolerant canola line DP-073496-4 is as safe for human consumption as food derived from conventional canola already in the food supply.

A decision has been made to approve the draft variation to Standard 1.5.2 to include food derived from herbicide-tolerant canola line DP-073496-4 in the Schedule.

1. Introduction

1.1 The Applicant

Pioneer Hi-Bred Australia Pty Ltd is a subsidiary of DuPont Pioneer, a multinational seed and technology provider to the agricultural sector and food industries.

1.2 The Application

Application A1089 was submitted on 7 June 2013. The Application seeks approval for food derived from genetically modified (GM) canola line DP-073496-4 under Standard 1.5.2 – Food produced using Gene Technology.

Canola line DP-073496-4 (herein abbreviated to line 73496) is tolerant to glyphosate herbicide through the introduction of *gat4621*, a gene constructed from native gene sequences from the bacterial species, *Bacillus licheniformis*. The introduced gene encodes GAT4621, an enzyme that chemically inactivates the herbicide, producing a metabolite with no herbicidal activity.

The GAT4621 protein is not new to the food supply. Expression of this protein has been used to confer tolerance to glyphosate in soybean (line DP-356043-5) and maize (corn line DP-098140-6), which have been assessed previously and approved by FSANZ.

1.3 The current Standard

Pre-market approval is necessary before food derived from a GM crop 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 or novel protein from an approved 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, on a case-by-case basis.

1.4 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.

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 assessment focuses on the safety of GM food for human consumption. Some submissions received for this Application raised issues that are outside the scope of FSANZ's regulatory scrutiny. For example, the application of gene technology to produce food, the potential impact of growing GM crops on organic producers, the environment and biodiversity, possible adverse impacts on trade, the perceived dominance of multinational biotechnology developers; the safety of GM animal feed and products from animals that consume GM feed were all discussed as reasons for rejecting the Application.

Environmental issues relating to the commercial growing of GM crops including the potential for adverse impacts on other organisms and human health (in an occupational context) are considered in Australia by the Office of the Gene Technology Regulator (OGTR), and in New Zealand by the Environmental Protection Authority.

In terms of safety related issues, a number of concerns were expressed that do not specifically apply to canola line 73496, but instead relate to the GM process itself, particularly the methods and genetic elements commonly used to transform plants. All of the comments received relating to general safety issues have been expressed in previous submissions and have been considered by FSANZ over the course of successive assessments of GM food applications. FSANZ has published numerous information sheets on its website that address these issues (see <http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx> and <http://www.foodstandards.gov.au/consumer/gmfood/gmoverview/Pages/default.aspx>).

Comments also frequently relate to the use of agricultural chemicals on food-producing crops. Any food safety risks associated with the use of agricultural or veterinary chemicals on both conventional and GM crops are already effectively managed through separate and well-established regulatory processes. Further information on the regulation of herbicide usage is in Table 1 below.

Responses to a number of general safety issues are summarised in Table 1. No changes to the safety assessment of canola 73496 (SD1) were considered necessary following consideration of the issues in this case.

Table 1: Summary of general issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>The use of gene technology to produce food creates many safety concerns; current protocols for testing transgenic foods and inadequate.</p>	<p>Physicians & Scientists for Global Responsibility</p>	<p>The approach used by FSANZ to assess the safety of GM food is based on core principles developed internationally almost 20 years ago, and published as guidelines by the Codex Alimentarius Commission (Codex, 2003; Codex, 2004). Over time, the comparative assessment has been the subject of scientific scrutiny and debate; 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>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. 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>Studies cited as evidence of safety concerns with certain GM foods have been examined by FSANZ, other regulators and independent scientists 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>Farmers use more herbicides on transgenic plants. Exposure to glyphosate is related to allergic reactions, irritable bowel syndrome, digestion problems, chronic fatigue, headaches, lethargy, skin complaints such as acne and eczema. Exposure to glyphosate-tolerant canola could potentially present similar results.</p>	<p>Physicians & Scientists for Global Responsibility</p>	<p>The use of herbicide-tolerant crops typically results in a different pattern of usage of a particular herbicide, rather than an increase overall. Glyphosate is permitted for use on over 60 food plant species; the majority of these are not genetically modified.</p> <p>Residues of approved agricultural chemicals are subject to strict government regulation in Australia and New Zealand and most trading countries. Residues 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 any residues of chemicals are kept as low as possible and consistent with the approved use of the chemical product to control pests and diseases of plants and animals. As such, MRLs apply to both conventional and GM crops alike. For further details see the FSANZ website at http://www.foodstandards.gov.au/consumer/chemicals/maxresidue/Pages/default.aspx</p>
<p>Horizontal gene transfer to gut bacteria and safety of ingesting recombinant DNA / transgenes</p>	<p>Physicians & Scientists for Global Responsibility</p>	<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> <p>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, such as fresh fruit and vegetables and meat. There is no difference in terms of risk to human health between DNA from a transgenic plant and DNA already present in our diet.</p>
<p>Potential allergenicity of GM foods</p>	<p>Physicians & Scientists for Global Responsibility</p>	<p>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).</p> <p>Any novel proteins likely to be present in a GM food undergo individual assessment for both allergenicity and toxicity.</p> <p>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.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>Lack of consideration of feeding studies in the safety assessment</p>	<p>Physicians & Scientists for Global Responsibility</p>	<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 several 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., 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.

2.1.2 Specific issue raised

2.1.2.1 Pure canola oil could contain small amounts of protein from seed thereby presenting a risk of allergy or food intolerance

The Physicians & Scientists for Global Responsibility suggested that, while in theory pure canola oil would contain no novel proteins to cause allergies, small amounts of seed proteins can remain in the oil and could be sufficient to trigger an allergic reaction. They further suggest that it is nevertheless more common for a person to be intolerant to canola oil, or to react to a common preservative in the oil. That canola oil is used in a substantial range of food products increases the likelihood of such a reaction.

Response

It is certainly possible for small amounts of seed proteins to remain in vegetable oils, with amounts likely to be variable depending on the extraction and refining processes used in each case. Canola oil is generally highly refined. However, as the proportion of novel protein (from the genetic modification) is only around 0.002% of total seed protein, dietary exposure to the novel protein (GAT4621), in this case is expected to be virtually zero (see section 4.2.1 in the Safety Assessment; SD1).

Notwithstanding the theoretical dietary exposure calculations, the assessment of potential allergenicity (see section 4.4 in the Safety Assessment) provides convincing evidence that the novel protein is readily degraded under normal digestive conditions, and lacks characteristics of common allergens. The conclusion from this and previous assessments of the GAT4621 protein is that it is unlikely to be allergenic in humans.

The compositional analysis has confirmed no significant differences between canola line 73496 and conventional varieties already in the food supply. Oil is extracted and processed in the same way regardless of whether the seed was obtained from GM or non-GM plants. Therefore, the possibility of an adverse reaction (eg. food intolerance or allergy) to other substances that might be present in canola oil (eg. a preservative) would be the same regardless of whether the oil was derived from non-GM canola or from canola line 73496. The occurrence of allergies or food intolerances in association with the consumption of canola oil therefore provides no grounds on which to reject canola line 73496.

2.2 Safety assessment

The safety assessment of canola line 73496 is provided in the supporting document (SD1) and included the following key elements:

- a characterisation of the transferred gene, its origin, function and stability in the canola 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 protein to be either allergenic or toxic in humans.

The assessment of canola line 73496 was confined to food safety and human nutritional issues. Any potential risks related to the release into the environment of GM plants, or their use as animal feed, or the safety of foods from animals consuming GM feed have not been addressed in this assessment. These are matters for others, such as the OGTR.

The Applicant for A1089 complied with all of the data requirements stipulated in the *Application Handbook* (FSANZ, 2011) for the safety assessment of GM food and, upon assessment of those data, FSANZ is satisfied that sufficient evidence was provided to demonstrate the safety of the food.

On the basis of the scientific data provided in the present Application, and other available information, food derived from canola line 73496 is as safe for human consumption as food derived from conventional canola varieties.

2.3 Risk management

2.3.1 Labelling

GM foods are labelled to help consumers make an informed choice.

In accordance with Standard 1.5.2, approved GM food must be labelled as 'genetically modified' if novel DNA or novel protein is present in the final food, or if it has altered characteristics.

Canola oil is the primary food product to be made from canola line 73496. Refined oils typically do not contain novel protein or novel DNA, however this should be determined on a case-by-case basis by food manufacturers. Minor uses of whole seeds from canola line 73496, for example in bakery products, would likely require labelling as 'genetically modified'.

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.

In the case of canola line 73496, the purpose of the genetic modification was not to alter the nutritional profile of the food, but rather to introduce an agronomic trait of potential use to growers. The compositional analysis of canola line 73496 confirmed that it is not significantly different to conventional canola in terms of the levels of key nutrients, antinutrients and other more minor components. Food derived from canola line 73496 is therefore not considered to have altered characteristics for the purposes of GM 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-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, a DNA analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the Applicant for canola line 73496 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 13 December 2013 and 31 January 2014. The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media portals and the publication, *Food Standards News*. Subscribers and interested parties were also notified.

Six submissions were received; three submitters supported the Application, while three expressed opposition to the approval of canola line 73496 (see section 2.1). Application A1089, including submissions received, is available on the FSANZ website.

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

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.

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 Applicant has indicated that canola line 73496 would be suitable for growing in Australia as well as in canola producing regions of North America. Cultivation in Australia (both field trials and commercial release) requires a separate, independent assessment by the OGTR, including an assessment of any environmental impact, before commercial release could be permitted. The Applicant has requested approval from the OGTR, and following its assessment, the OGTR has approved field trials, a necessary precursor to future commercial production of the crop in Australia. There is no intention to grow canola line 73496 in New Zealand, however oil derived from this line could enter the food supply through imported foods, once the decision to commercialise the crop overseas has been made.

The direct and indirect benefits to the community, Government and industry outweigh the costs that would arise from a food regulatory measure developed or varied as a result of the application.

The points below list the effect that approving the draft would be expected to have on various sectors. The analysis is necessarily speculative and based on the assumption that canola line 73496 will be approved for commercial cultivation in other countries (see section 2.5.1.4).

Consumers: Broader availability of imported foods containing canola, if line 73496 were to be approved for commercial growing overseas.
The safety assessment found there would be no impact on public health and safety if food derived from canola line 73496 were to be introduced into the food supply.

For those canola line 73496 products containing novel DNA or novel protein, required labelling would allow consumers wishing to avoid them to do so.

Government: Benefit that if canola line 73496 was detected in canola imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of canola line 73496 would ensure no conflict with WTO responsibilities if the line is approved for commercial growing in other countries.

Industry: Importers of processed foods containing canola line 73496 would benefit as foods derived from this line would be compliant with the Code, allowing broader market access and increased choice in raw materials.

Retailers may be able to offer a broader range of imported food products manufactured overseas using derivatives of canola line 73496.

Possible cost to the food industry as some foods containing canola line 73496 would require labelling according to the provisions in the Code.

The segregation of raw agricultural commodity of canola line 73496, 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 derived from canola line 73496 has been found to be as safe as food from conventional canola varieties, not approving a draft variation would offer little benefit to consumers, as approval of canola line 73496 by other countries could limit the availability of imported products in the Australian and New Zealand markets. In addition, this option would result in the requirement for segregation of any products containing canola line 73496, which would be likely to increase the costs of importing foods.

Also, not approving a draft variation is likely to be inconsistent with Australia's and New Zealand's WTO obligations if canola line 73496 is approved for commercial growing in other countries.

Based on the conclusions of the safety assessment, 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 is seeking regulatory approval of canola line 73496 in several other countries, as listed in Table 2. In addition to the jurisdictions listed, the Applicant has indicated that submissions will be made for import approvals in other international markets where established regulatory review processes are in place.

It is the Applicant's intention that canola line 73496 will be commercially cultivated in major canola growing regions in Canada, other parts of North America and in Australia, but not in New Zealand.

Table 2: List of countries to whom applications for regulatory approval of canola line 73496 have been submitted (updated 31 January 2014)

Country	Agency	Request/status
USA	Department of Agriculture (USDA)	Cultivation – approved July 2013.
	Environmental Protection Agency (EPA)	Amend residue definition, submitted February 2011.
	Food and Drug Administration (USFDA)	Food and feed safety, completed in May 2012.
Canada	Canadian Food Inspection Agency (CFIA)	Environment and animal feed, approved May 2012.
	Health Canada (HC)	Food, approved May 2012.
Japan	Ministry of Health, Labor, and Welfare (MHLW)	Food use, submitted January 2013.
	Ministry of Agriculture, Forestry and Fisheries (MAFF)	Environment/import and feed, submitted July 2012 and April 2013 respectively.
Korea	Ministry of Food and Drug Safety (Formerly Korea Food and Drug Administration)	Food approval, submitted November 2012.
	Rural Development Administration (RDA)	Feed approval, submitted November 2012.
Mexico	Department of Health	Food and feed, approved in July 2012.
European Union	European Food Safety Authority (EFSA)	Food and feed for import, submitted May 2012.

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 canola line 73496 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 scientific evidence, including detailed studies provided by the Applicant, food derived from canola line 73496 is as safe as food derived from other commercial canola varieties already in the food supply.

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

In accordance with Standard 1.5.2, food derived from canola line 73496 would be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein, or if it has altered characteristics. Food derived from canola line 73496 does not have altered characteristics.

Oil from canola line 73496 would be the primary food product. Canola oil is typically highly refined, and novel protein and novel DNA are unlikely to be present. Minor use of whole canola seeds as ingredients in bakery products has been observed. Whole seeds from canola line 73496 would likely contain novel protein and novel DNA, and would therefore require labelling (see Section 2.3.1).

2.5.2.3 *The prevention of misleading or deceptive conduct*

The requirement for detection methodology as outlined in Section 2.3.2 addresses 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 canola line 73496 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 were 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 an assessment has found no safety concerns, generally allows for innovation by developers and a widening of the technological base for the production of foods. Canola line 73496 is a new crop intended to provide growers of canola with an alternative to existing weed management strategies.

- **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 canola line 73496.

- **Any written policy guidelines formulated by the Ministerial Council⁴**

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 (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

⁴ Now known as the COAG Legislative and Governance Forum on Food Regulation

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



Food Standards (Application A1089 – *Food derived from Herbicide-tolerant Canola Line DP-073496-4*) 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 A1089 – Food derived from Herbicide-tolerant Canola Line DP-073496-4) 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

“

	1.5	Food derived from herbicide-tolerant canola line DP-073496-4	
--	-----	---	--

”

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 A1089 which seeks approval for herbicide-tolerant canola line DP-073496-4 which is genetically modified for tolerance to glyphosate. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation⁵, 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

The Authority has approved herbicide-tolerant canola line DP-073496-4 to be listed in the Schedule to Standard 1.5.2 Food produced using Gene Technology. This variation permits the sale or use of food derived from canola line DP-073496-4 in Australia and New Zealand.

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 A1089 included one round of public consultation following an assessment and the preparation of a draft variation to the Standard and associated report. Submissions were invited on 13 December 2013 for a seven-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 herbicide-tolerant canola line DP-073496-4 to the Schedule to Standard 1.5.2.