

**13 December 2013**  
**[23–13]**

## **Call for submissions – Application A1089**

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

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FSANZ has assessed an Application from Pioneer Hi-Bred Australia Pty Ltd seeking permission for food derived from canola line DP-073496-4, which is genetically modified to provide tolerance to the herbicide glyphosate, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

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

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

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

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

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

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 31 January 2014**

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

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

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

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## Supporting documents

The following document which informed the assessment of this Application is available on the FSANZ website at

<http://www.foodstandards.gov.au/code/applications/Pages/A1089.aspx>

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

## 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.

This Application is being assessed under the General Procedure.

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

The safety assessment of 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 canola line DP-073496-4 is considered as safe for human consumption as food derived from conventional canola already in the food supply.

FSANZ has prepared a draft variation to Standard 1.5.2 to include food derived from canola line DP-073496-4.

# 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 and/or novel protein from an approved GM variety is present in the final food, or the food has altered characteristics. In the latter case, the Standard also allows for additional labelling about the nature of the altered characteristics 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 is being assessed under the General Procedure.

## **2 Summary of the assessment**

### **2.1 Risk 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 risks related to the release into the environment of GM plants used in food production, or the safety of their use as animal feed, or animals consuming feed derived from GM plants have not been addressed in this assessment.

No potential public health and safety concerns were identified. 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.

The release of canola line 73496 into the Australian environment would need to be independently assessed by the Office of the Gene Technology Regulator (OGTR). There are no plans to grow canola line 73496 in New Zealand or otherwise release it into the environment in that country. In New Zealand, environmental release would need to be assessed independently by the Environmental Protection Authority (EPA).

### **2.2 Risk management**

Two regulatory options were considered: (1) prepare a draft variation to Standard 1.5.2 to include food derived from canola line 73496; or (2) reject the Application.

FSANZ has decided to prepare a draft variation to Standard 1.5.2 because approval of food derived from canola line 73496 raises no public health and safety concerns, and because the potential benefits of approving the variation outweigh the potential costs.

### **2.3 Risk communication**

#### **2.3.1 Consultation**

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

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

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

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

The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the assessment.

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

### **2.3.2 World Trade Organization (WTO)**

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

There are no relevant international standards and amending the Code to permit food derived from herbicide-tolerant canola line 73496 is unlikely to have a significant effect on international trade as it would permit food derived from herbicide-tolerant canola line 73496 to be imported into Australia and New Zealand and sold, where currently sale is prohibited. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## **2.4 FSANZ Act assessment requirements**

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

### **2.4.1 Section 29**

#### **2.4.1.1 Cost benefit analysis**

A consideration of the costs and benefits of the regulatory options is not intended to be an exhaustive, quantitative financial analysis of the options, as most of the impacts 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.

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

#### *Option 1 – Develop a draft variation to Standard 1.5.2*

Consumers: Broader availability of imported food products as there would be no restriction on any foods containing canola line 73496.

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

Appropriate labelling would enable consumers to avoid those GM canola products that contain novel DNA or novel protein in the final food.

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

Approval would ensure no conflict with WTO responsibilities.

In the case of approved GM foods, monitoring is required to ensure compliance with the labelling requirements, and in the case of GM foods that have not been approved, monitoring is required to ensure they are not illegally entering the food supply. The costs of monitoring are thus expected to be comparable, whether a GM food is approved or not.

Industry: Importers of processed foods containing canola oil or whole seeds from canola line 73496 would benefit as they 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 foods containing canola products.

Possible cost to food industry as some foods containing canola line 73496 would be required to be labelled.

#### *Option 2 – Reject application*

Consumers: Possible restriction on imported food products, to those not containing canola line 73496.

No effect on consumers wishing to avoid GM foods, as food from canola line 73496 is not currently permitted in the food supply.

Potential increase in price of certain imported foods due to requirement for segregation of canola line 73496.

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

Industry: Possible restriction on imports of certain food products if canola line 73496 were to be commercialised overseas.

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

As food from canola line 73496 has been found to be as safe as food from conventional canola varieties, not preparing a draft variation would offer little benefit to consumers, as approval of canola line 73496 by other countries could limit the availability of certain imported food products in the Australian and New Zealand markets.

In addition, option 2 would result in the requirement for segregation of any products containing canola line 73496 from those containing approved canola lines, which would be likely to increase the costs of imported canola-derived foods.

The costs that would arise from a food regulatory measure developed or varied as a result of the Application therefore do 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.

#### **2.4.1.2 Other measures**

There were no other measures (whether available to FSANZ or not) that could achieve the same result and be more cost-effective than an amendment to Standard 1.5.2.

#### **2.4.1.3 Any relevant New Zealand standards**

Standard 1.5.2 applies in New Zealand.

#### **2.4.1.4 Any other relevant matters**

The Applicant is seeking regulatory approval of canola line 73496 in several other countries, as listed in Table 1. In addition to the jurisdictions listed in the Table, the Applicant has indicated that submissions will be made for import approvals in other key 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. Cultivation in Australia would require a separate, independent assessment by the Office of the Gene Technology Regulator (OGTR), including an assessment of any environmental impact, before commercial release could be permitted.

**Table 1: List of countries to whom applications for regulatory approval of canola line 73496 have been submitted**

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

#### **2.4.2 Subsection 18(1)**

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

#### **2.4.2.1 Protection of public health and safety**

Food derived from canola line 73496 has been assessed according to the safety assessment guidelines prepared by FSANZ (2007).

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.

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

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

In accordance with Standard 1.5.2, food derived from 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 contain novel protein and novel DNA, and would therefore require labelling if used as an ingredient.

#### **2.4.2.3 The prevention of misleading or deceptive conduct**

##### *Detection methodology*

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions has been formed by the Implementation Sub-Committee for Food Regulation [ISFR is a subcommittee of the Food Regulation Standing Committee (FRSC)] to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM food applications. The EAG has indicated that for GM foods, the full nucleotide sequence of the inserted DNA and adjacent genomic DNA are sufficient data to be provided. Using this information, an analytical laboratory would be able to develop a PCR-based detection method. The relevant sequence information for canola line 73496 has been supplied by the Applicant to satisfy the requirement for detection methodology in the FSANZ Application Handbook (FSANZ, 2011).

#### **2.4.3 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 accordance with specific demands in the FSANZ *Application Handbook* (FSANZ 2011).

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, providing there are no safety concerns, allows for innovation by developers and a widening of the technological base for the production of foods. Canola line 73496 is a new crop designed to provide growers wherever canola is grown around the world with an alternative to existing weed management strategies.

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

The cost/benefit analysis in Section 2.4.1, lists a number of considerations that address fair trading with respect to canola line 73496.

- **any written policy guidelines formulated by the Ministerial Council<sup>1</sup>.**

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

### **3 Draft variation**

The draft variation to Standard 1.5.2 is at Attachment A. The draft variation is intended to take effect on gazettal.

A draft 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.

### **4 References**

Codex (2004) *Principles for the risk analysis of foods derived from modern biotechnology*. Report No. CAC/GL 44-2003, Codex Alimentarius Commission, Rome.

[http://www.codexalimentarius.net/web/standard\\_list.do?lang=en](http://www.codexalimentarius.net/web/standard_list.do?lang=en).

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](http://www.foodstandards.gov.au/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf).

FSANZ (2011) *Application Handbook*. Prepared by Food Standards Australia New Zealand.

<http://www.foodstandards.gov.au/foodstandards/changingthecode/applicationshandbook.cfm>.

### **Attachments**

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

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<sup>1</sup> Now known as the COAG Legislative and Governance Forum on Food Regulation

## Attachment A – 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

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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 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

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	1.5	Food derived from herbicide-tolerant canola line DP-073496-4	
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## **Attachment B – Draft Explanatory Statement**

### **1. Authority**

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

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

FSANZ accepted Application A1089 which seeks permission for the sale and use of food derived from herbicide-tolerant canola line DP-073496-4. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to a Standard.

### **2. Purpose**

Standard 1.5.2 currently sets out the permission and conditions for the sale and use of foods produced using gene technology. Food derived from canola line DP-073496-4 is not currently listed in the Schedule to Standard 1.5.2 and, as such is not permitted for sale or use in food. Therefore, FSANZ is proposing to vary Standard 1.5.2 by inserting into the Schedule a reference to food derived from herbicide-tolerant canola line DP-073496-4.

### **3. Documents incorporated by reference**

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

### **4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1089 will include one round of public consultation following an assessment and the preparation of a draft variation.

A Regulation Impact Statement (RIS) was not required because the use of food derived from canola line DP-073496-4, if approved, would be voluntary and would be likely to have a minor impact on business and individuals.

### **5. Statement of compatibility with human rights**

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

### **6. Variation**

Item 1 adds food derived from herbicide-tolerant canola line DP-073496-4 into the Schedule to Standard 1.5.2.