

**17 December 2012**  
**[29-12]**

Approval Report – Application A1071

Food derived from Herbicide-tolerant Canola Line MON88302

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Monsanto Australia Limited (Monsanto) seeking permission for food derived from canola line MON88302 genetically modified to provide tolerance to the herbicide glyphosate.

On 17 August 2012, FSANZ sought submissions on a draft variation to a standard and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation to the Standard on 6 December 2012. The COAG Legislative and Governance Forum on Food Regulation<sup>1</sup> (the Forum) was notified of FSANZ's decision on 13 December 2012.

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

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<sup>1</sup> Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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### Supporting documents

The following document used to prepare this Report is available on the FSANZ website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1071food5499.cfm>

SD1: Safety Assessment

# 1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Limited (Monsanto) on 26 March 2012. The Applicant requested a variation to Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code*, to permit the sale and use of food derived from genetically modified (GM) canola line MON88302, which is tolerant to the herbicide glyphosate.

This Application was assessed under the General Procedure.

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 MON88302 is provided in Supporting Document 1 (SD1). No potential public health and safety concerns were identified. Based on the data provided in the present Application, and other available information, food derived from canola line MON88302 is considered to be as safe for human consumption as food derived from conventional canola cultivars.

A decision has been made to approve the draft variation to Standard 1.5.2 to include food derived from herbicide-tolerant canola line MON88302 in the Schedule.

## **2. Introduction**

### **2.1 The Applicant**

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

### **2.2 The Application**

Application A1071 was submitted by Monsanto Australia Limited on 26 March 2012. It sought approval for food derived from line MON88302 under Standard 1.5.2 – Food produced using Gene Technology.

Canola line MON88302 is tolerant to the herbicide glyphosate. Tolerance is achieved through the introduction of the *cp4 epsps* gene, from the soil bacterium *Agrobacterium* sp. expressing the protein 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS). EPSPS proteins have been widely used to confer glyphosate tolerance in a range of GM crop species. The Applicant claims that, compared with a previous glyphosate-tolerant canola (GT73 - Application A363), MON88302 tolerates higher levels of glyphosate and permits greater flexibility in the stage at which the glyphosate can be applied.

### **2.3 The current Standard**

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

### **2.4 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)
- 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
- there was no other relevant matter to consider.

### **2.5 Procedure for assessment**

The Application was assessed under the General Procedure.

## **2.6 Decision**

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

The approved variation to the Standard is at Attachment A.

An Explanatory Statement is at Attachment B.

## **3. Summary of the findings**

### **3.1 Risk assessment**

The safety assessment of canola line MON88302 is provided in SD1 and included the following key elements:

- a characterisation of the transferred genes, their 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 proteins to be either allergenic or toxic in humans.

The assessment of canola line MON88302 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 the safety of 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 data provided in the present Application, and other available information, food derived from canola line MON88302 was considered to be as safe for human consumption as food derived from conventional canola cultivars.

### **3.2 Risk management**

#### **3.2.1 Labelling**

In accordance with the labelling provisions in Standard 1.5.2, food derived from canola line MON88302 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein, or has altered characteristics. Food from MON88302 does not have altered characteristics.

For human consumption, seed from canola is mostly processed into oil which, because of processing, is unlikely to contain any novel protein or novel DNA. Oil from MON88302 would therefore be unlikely to require labelling.

MON88302 seed used in bakery products would require labelling.

### 3.2.2 Detection methodology

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions has been formed by the Food Regulation Standing Committee - Implementation Sub-Committee 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. Using this information, any analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the Applicant for MON88302 to satisfy the requirement for detection methodology in the FSANZ Application Handbook (FSANZ, 2011).

### 3.2.3 Summary of submissions

Consultation is a key part of FSANZ's standards development process. 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. While not all comments in submissions can be taken on board, they are valued and all contribute to the rigour of our assessment.

Public submissions were invited on a draft variation which was released for public comment between 17 August and 27 September 2012. Six submissions were received.

Responses to two general issues raised or implied, are available from the FSANZ website (see Table 1).

**Table 1: Summary of issues raised in submissions**

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<b>Inappropriate approval system used by FSANZ</b>	Sue David	A detailed description of the process involved in the FSANZ safety assessment of GM foods is available on the FSANZ website at <a href="http://www.foodstandards.gov.au/srcfiles/GM%20Foods_text_pp_final.pdf">http://www.foodstandards.gov.au/srcfiles/GM%20Foods_text_pp_final.pdf</a>  The conduct of the safety assessment is subject to strict requirements outlined in the <i>Application Handbook</i> <sup>2</sup> . In turn, these requirements are guided by concepts and principles developed through the work of the Organisation for Economic Cooperation and Development, Food and Agriculture Organization of the United Nations, World Health Organisation and Codex Alimentarius Commission.

<sup>2</sup> The *Application Handbook* is available at <http://www.foodstandards.gov.au/foodstandards/changingthecode/applicationshandbook.cfm>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Adverse health effects of GM foods	Sue David Mandy O'Neil	A consideration of literature that purports to show adverse health effects of GM food is available on the FSANZ website at <a href="http://www.foodstandards.gov.au/consumerinformation/gmfoods/gmtableofstudies.cfm">http://www.foodstandards.gov.au/consumerinformation/gmfoods/gmtableofstudies.cfm</a>  <a href="http://www.foodstandards.gov.au/consumerinformation/gmfoods/gmfactsheets/responsetosralinipap5676.cfm">http://www.foodstandards.gov.au/consumerinformation/gmfoods/gmfactsheets/responsetosralinipap5676.cfm</a>

### 3.3 Risk communication

FSANZ developed and applied a basic communication strategy to this Application. 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.

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

Application A1071, including submissions received, is available on the FSANZ website.

## 4. Reasons for decision

The variation to the Code to permit the sale and use of food derived from herbicide-tolerant canola line MON88302 in Australia and New Zealand was approved based on available evidence, for the following reasons:

- The safety assessment did not identify any public health and safety concerns associated with the genetic modification used to produce canola line MON88302.
- Food derived from canola line MON88302 is equivalent to that derived from the conventional counterpart and other commercially available canola cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of food derived from canola line MON88302 will be required in the ingredients list or in conjunction with the name of the food, if it contains novel DNA or novel protein.
- There were no measures that would be more cost-effective than a variation to Standard 1.5.2 and could achieve the same end.

### 4.1 Section 29

FSANZ had regard to the following matters under section 29 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweighed the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- there were no other measures that would be more cost-effective than a variation to Standard that could achieve the same end

- any relevant New Zealand standards
- any other relevant matters.

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

#### 4.1.1 Cost/benefit analysis

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.

Consumers: Broad availability of imported canola products as there would be no restriction on imported foods containing canola line MON88302.

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

Government: Benefit that if canola line MON88302 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 MON88302 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 derivatives would benefit as foods derived from canola line MON88302 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 canola products or imported foods manufactured using canola derivatives.

Possible increased cost to food industry as some food ingredients derived from canola line MON88302 would be required to be labelled.

As food from canola line MON88302 has been found to be as safe as food from conventional cultivars of canola, not preparing a draft variation would offer little benefit to consumers, as approval of canola line MON88302 by other countries could limit the availability of imported canola 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 MON88302 from those containing approved canola lines which would be likely to increase the costs of imported canola-derived foods.

Also, not preparing a draft variation was considered likely to be inconsistent with Australia's and New Zealand's WTO obligations.

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

#### **4.1.2 Other measures**

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

#### **4.1.3 Relevant New Zealand standards**

Standard 1.5.2 applies in New Zealand.

#### **4.1.4 Any other relevant matters**

A completed consultation letter was issued by the US Food and Drug Administration in April 2012 regarding the food and feed safety of MON88302. Health Canada completed an approval for food use of MON88302 in June 2012 and the Canadian Food Inspection Agency completed an approval for its environmental release and use in animal feed in June 2012.

Monsanto has requested a Determination of Nonregulated Status for MON88302, including all progenies derived from crosses between MON88302 and conventional canola or other canola lines previously deregulated in the United States, from the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Monsanto has submitted dossiers to the Korean Food and Drug Administration and Rural Development Administration; Japan's Ministry of Health, Labour, and Welfare and Ministry of Forestry and Fisheries; and to the European Food Safety Authority. Submissions have also been made in the Philippines, Singapore, Mexico and China

The Applicant has indicated that an application will be made at a future date for a licence from the Gene Technology Regulator to grow MON88302 commercially in Australia. There is currently no intention to apply for approval to cultivate this line in New Zealand. Such cultivation in New Zealand would need to be independently assessed by the Environmental Protection Authority.

## **4.2 Addressing FSANZ's objectives for standards setting**

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

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

Food derived from canola line MON88302 was assessed according to the safety assessment guidelines prepared by FSANZ (2007).

No public health and safety concerns were identified in the safety assessment. On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from canola line MON88302 is considered as safe and wholesome as food derived from commercial, conventional canola cultivars.

### **4.2.2 The provision of adequate information relating to food to enable consumers to**

## **make informed choices**

In accordance with existing labelling provisions, food derived from canola line MON88302 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein.

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

The requirement for detection methodology (see Section 3.2.2) is designed to address this objective.

### **4.2.4 Subsection 18(2) considerations**

FSANZ has also had regard to the objectives set out in subsection 18(2):

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

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex General Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2004). Based on these principles, the risk analysis undertaken for canola line MON88302 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, 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 MON88302 is a new food crop designed to provide growers in a number of countries around the world with an alternative weed management strategy.

- *The promotion of fair trading in food*

The cost/benefit analysis in Section 4.1 lists a number of considerations that address fair trading with respect to canola line MON88302.

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

There are no relevant guidelines.

## **4.3 Implementation**

The variation will take effect on gazettal.

## **5. References**

Codex (2004) *Principles for the risk analysis of foods derived from modern biotechnology*. Report No.

CAC/GL 44-2003, Codex Alimentarius Commission, Rome.  
[http://www.codexalimentarius.net/web/standard\\_list.do?lang=en](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%202\\_.pdf](http://www.foodstandards.gov.au/srcfiles/GM%20FINAL%20Sept%2007L%202_.pdf).

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

## **Attachments**

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

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



### **Food Standards (Application A1071 – Food derived from Glyphosate-tolerant Canola MON88302) 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 X

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

**1 Name**

This instrument is the *Food Standards (Application A1071 – Food derived from Glyphosate-tolerant Canola MON88302) Variation*.

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

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

**3 Commencement**

These variations commence on the **date of gazettal**.

**SCHEDULE**

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

“ 1.4 Food derived from herbicide-tolerant canola line MON88302 ”

## **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).<sup>3</sup>

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 A1071 which seeks permission for the sale and use of food derived from herbicide-tolerant canola line MON88302. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to a Standard.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation<sup>3</sup>, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the 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 and operation**

As it is not listed in the Schedule to Standard 1.5.2, food derived from canola line MON88302 is not currently permitted for sale or use in food. The Authority has approved a variation to Standard 1.5.2 to permit the sale, or use in food, of food derived from canola line MON88302 in the Schedule.

### **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 A1071 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 17 August 2012 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.

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<sup>3</sup> Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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

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

**6. Variation**

This item adds food derived from canola line MON88302 into the Schedule to Standard 1.5.2.