

17 August 2012
[18-12]

Call for submissions – Application A1071

Food derived from Herbicide-tolerant Canola Line MON88302

FSANZ has assessed an Application made by Monsanto Australia Ltd (Monsanto) seeking permission for food derived from canola line MON88302, 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.

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 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 27 September 2012.

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.

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/foodstandards/applications/applicationa1071food5499.cfm>

SD1 Safety Assessment Report: Application A1071 – Food derived from Herbicide-tolerant Canola Line MON88302

1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Ltd (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* (the Code), to permit the sale and use of food derived from genetically modified (GM) canola line MON88302, conferring tolerance to 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 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 forms the central component in considering an application.

The safety assessment of canola line MON88302 is provided in Supporting Document 1. No potential public health and safety concerns have been identified. On the basis of 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.

FSANZ has prepared a draft variation to the Code to include food derived from canola line MON88302 in Standard 1.5.2.

2. Introduction

2.1 The Applicant

Monsanto Australia Limited is part of Monsanto. The company is a technology provider to the agricultural and food industries.

2.2 The Application

Application A1071 – Food derived from herbicide-tolerant canola line MON88302, 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, in the *Australia New Zealand Food Standards Code* (the Code).

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 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.

2.4 Reasons for accepting 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]

2.5 Procedure for assessment

The Application is being assessed under the General Procedure.

3. Summary of the assessment

3.1 Risk assessment

The safety assessment of canola line MON88302 is provided in the supporting document

(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 have been identified.

On the basis of 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.

3.2 Risk Management

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:

- whether costs that would arise from a food regulatory measure varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation of the food regulatory measure
- whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure varied as a result of the Application.
- 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 for the OBPR to be informed about GM food applications.

Two regulatory options were considered: (1) rejection of the Application; or (2) preparation of a draft variation to Standard 1.5.2 to include food derived from canola line MON88302.

3.2.1 Cost/benefit analysis

A consideration of the cost/benefit of the regulatory options 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.

Option 1 – Develop a draft variation to Standard 1.5.2

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

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

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 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.

Option 2 – Reject application

Consumers: Possible restriction in the availability of imported canola products to those products that do not contain canola line MON88302.

No impact on consumers wishing to avoid GM foods, as food from canola line MON88302 is not currently permitted in the food supply.

Potential increase in price of imported canola foods due to requirement for segregation of canola line MON88302.

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

Industry: Possible restriction on imports of canola food products if canola line MON88302 were to be commercialised overseas.

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

3.2.2 Other measures

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

3.2.3 Relevant New Zealand standards

Standard 1.5.2 applies in New Zealand.

3.2.4 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 and Singapore.

The Applicant has stated that MON88302 regulatory submissions will be made to countries that import significant canola or food and feed products derived from US, Canadian and Australian canola including 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 could have an impact on the environment, which would need to be independently assessed by the Environmental Protection Authority.

3.2.5 Addressing FSANZ's objectives for standards-setting

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

3.2.5.1 Protection of public health and safety

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

No public health and safety concerns were identified in this 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 other commercial canola cultivars.

3.2.5.2 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 MON88302 would be required to be labelled as genetically modified if it contains novel DNA or novel protein or if it has altered characteristics. MON88302 does not have altered characteristics.

For human consumption, seed from canola is mostly processed into oil which, because of processing, contains negligible levels of any protein or DNA. Oil from MON88302 would therefore be unlikely to require labelling. MON88302 seed used in bakery products would require labelling.

3.2.5.3 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 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 has been supplied by the Applicant for MON88302 to satisfy the requirement for detection methodology in the FSANZ Application Handbook (FSANZ, 2011).

3.2.5.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed 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 GM foods applies concepts and principles outlined in the Codex General Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2004).

An Applicant for a GM food submits 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 is used in the safety assessment.

- *The promotion of consistency between domestic and international food standards.*

FSANZ assesses the safety of GM foods in accordance with internationally established scientific principles and guidelines developed through the work of the Organisation for Economic Cooperation and Development, Food and Agriculture Organization of the United Nations, World Health Organization and the Codex Alimentarius Commission. These principles and guidelines are, however, applied within the context of the Australian and New Zealand food regulatory framework.

- *The desirability of an efficient and internationally competitive food industry.*

The inclusion of GM 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.

- *The promotion of fair trading in food.*

The cost/benefit analysis in Section 3.2.1 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 for GM foods.

3.3. Risk communication

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

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.

FSANZ places all new applications on the FSANZ website and Application A1071 is available at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1071food5499.cfm>

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 COAG Legislative and Governance Forum on Food Regulation¹.

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

If the approval of food derived from herbicide-tolerant canola line MON88302 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.

3.3.1 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 MON88302 is unlikely to have a significant effect on international trade as it would permit food derived from herbicide-tolerant canola line MON88302 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.

4. Draft variation

The draft variation to Standard 1.5.2 is at Attachment A.

A draft Explanatory Statement is at Attachment B.

4.1 Implementation

The variation would 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.

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>.

Attachments

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

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



Food Standards (Application A1071 – Food derived from Glyphosate-tolerant Canola MON88302) 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 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.x Food derived from herbicide-tolerant canola line MON88302 ”

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 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 prepared a draft variation to a Standard.

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. Therefore, FSANZ is proposing to vary Standard 1.5.2 by including food derived from canola line MON88302 in the Schedule.

3. Documents incorporated by reference

The 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 A1071 has included one round of public consultation following an assessment and the preparation of a draft variation to a Standard. Submissions were called for on 17 August 2012 for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the use of food derived from canola line MON88302, 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

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