FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

12 May 2017
[12–17]

Call for submissions – Application A1140

Food derived from Herbicide-tolerant Canola Line MS11

FSANZ has assessed an Application made by Bayer CropScience to seek approval for food derived from canola line MS11 that has been genetically modified to confer two novel agronomic traits—tolerance to the broad spectrum herbicide glufosinate ammonium and expression of male sterility. A draft food regulatory measure has been prepared and, 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 that we accept as confidential, 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) 23 June 2017

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 document

The following document[1] which informed the assessment of this Application is available on the FSANZ website:

SD1 Safety Assessment Report

[1] http://www.foodstandards.gov.au/code/applications/Pages/A1140GMCanolaMS11.aspx

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Bayer CropScience on 9 December 2016. The Applicant requested a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to include food from a new genetically modified (GM) canola (*Brassica napus*) line, MS11. This canola line has been genetically modified to confer two novel agronomic traits—tolerance to the broad spectrum herbicide glufosinate ammonium and expression of male sterility.

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in section 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 a central part of considering an application.

The safety assessment of GM canola line MS11 is provided in Supporting Document 1. No potential public health and safety concerns have been identified. Based on the data provided in the Application, and other available information, food derived from line MS11 is considered to be as safe for human consumption as food derived from conventional canola cultivars.

FSANZ has prepared a draft variation to Schedule 26 that includes a permission for food derived from herbicide-tolerant canola line MS11.

1 Introduction

1.1 The Applicant

Bayer CropScience Pty Ltd (Bayer) is a technology provider to sectors including agriculture.

1.2 The Application

Application A1140 was submitted on 9 December 2016. It seeks a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to include food from a new genetically modified (GM) canola (*Brassica napus*) line, MS11. This canola line has been genetically modified to confer two novel agronomic traits—tolerance to the broad spectrum herbicide glufosinate ammonium (glufosinate) and expression of male sterility.

Tolerance to glufosinate is achieved through expression of phosphinothricin N- acetyltransferase (PAT) encoded by the *bar (bialaphos)* gene from *Streptomyces hygroscopicus*.

Male sterility is conferred by the *barnase* gene from *Bacillus amyloliquefaciens* that is expressed in developing anthers of MS11 canola. The Barnase protein causes RNA degradation, cell disruption, and ultimately death of the cells involved in pollen formation. Hence MS11 is unable to either self-pollinate or pollinate other plants, but the female reproductive parts of the flower remain functional. The Applicant's intention is to use the male sterile (MS) line in a hybrid breeding system in which MS11 (as the female parent line) is outcrossed with an agronomically-superior male line (the pollen donor) containing a protein (Barstar) which inhibits the Barnase protein, thus restoring fertility in the seed sown by the farmer. The plants germinating from this seed therefore show hybrid vigour, as well as being able to self-pollinate and produce seed that is harvested for the food/feed market.

MS11 also contains the *barstar* gene from *B. amyloliquefaciens*. The resulting Barstar protein is only weakly expressed and is not sufficient to override the effect of Barnase produced in the anther. However, it is sufficient to inhibit any Barnase that is inadvertently expressed in tissues other than the anther and which may adversely affect agronomic performance. Thus the presence of the *barstar* gene in MS11 assists in improving the quality of male-sterile lines identified during the selection phase.

The safety of all three proteins has previously been assessed by FSANZ.

1.3 The current standards

Pre-market approval is necessary before a GM food may enter the Australian and New Zealand food supply. Approval of such foods is contingent on completion of a comprehensive pre-market safety assessment. Standard 1.5.2 sets out the permission and conditions for the sale and use of food produced using gene technology (a GM food). Foods that have been assessed and approved are listed in Schedule 26.

Standard 1.5.2 also 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 (as defined in Standard 1.5.2) is present in the food.

Foods listed in subsections S26—3(2) and (3) in Schedule 26 must also be labelled with the words 'genetically modified', as well as any other additional labelling required by the Schedule, regardless of the presence of novel DNA or novel protein in the foods.

Foods listed in subsections S26—3(2) and (3) are considered to have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not produced using gene technology.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Safety assessment

In conducting a safety assessment of food derived from MS11, a number of criteria have been addressed including: a characterisation of the transferred gene sequences, their origin, function and stability in the canola genome; the changes at the level of DNA and protein in the whole food; compositional analyses; and evaluation of intended and unintended changes.

The assessment of MS11 was restricted to human food safety and nutritional issues. This assessment therefore does not address any risks to the environment that may occur as the result of growing GM plants used in food production, or any risks to animals that may consume feed derived from GM plants. The Applicant has indicated an intention to apply for commercial cultivation of MS11 in Australia. This would require independent assessment and approval by the Office of the Gene Technology Regulator. Should cultivation in New Zealand be sought, this would require assessment by the Environmental Protection Authority in New Zealand.

No potential public health and safety concerns have been identified.

Based on the data provided in the Application, and other available information, food derived from MS11 is considered to be as safe for human consumption as food derived from conventional canola cultivars.

2.2 Risk management

2.2.1 Labelling

It is noted that line MS11 itself is not intended as a direct food source but will be used in a hybrid breeding programme (see section 1.2). In accordance with labelling provisions in Standard 1.5.2 (see section 1.3), food derived from either MS11 itself or progeny containing the MS11 event would be required to be labelled as ‘genetically modified’ if it contains novel DNA or novel protein, or if it has altered characteristics. Food containing the MS11 event does not have altered characteristics.

Oil from canola lines containing the MS11 event would be the primary food product. Canola oil is typically highly refined, and novel protein and novel DNA are unlikely to be present. Oil from MS11 would therefore be unlikely to require labelling. Minor use of whole canola seeds as ingredients in bakery products has been observed. Whole seeds from canola line MS11 would contain novel protein and novel DNA, and would therefore require labelling if used as an ingredient. Protein isolate from MS11 would be likely to require labelling.

2.2.2 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-Committee[2] to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food derived from gene technology (GM applications).

The EAG indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the Applicant for A1140.

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, media release and 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.

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 on Food Regulation. 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 members 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. Although permission for food derived from MS11 to be imported into Australia and New Zealand and sold, would be a trade-liberalising measure, it is unlikely to have a significant effect on international trade.

[2] Now known as the Implementation Subcommittee for Food Regulation

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of 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 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010, granted a standing exemption from the need for the OBPR to assess if a Regulatory Impact Statement is required for the approval of genetically modified foods (ref 12065).

This standing exemption was provided as such changes are considered as minor, machinery and deregulatory in nature. The exemption relates to the introduction of a food to the food supply that has been determined to be safe.

Notwithstanding the above exemption, FSANZ conducted a cost benefit analysis. That analysis found the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the costs to the community, government or industry that would arise from the development or variation of that measure.

A consideration of the cost/benefit of the regulatory options is not intended to be an exhaustive, quantitative financial analysis of the options as 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 options below are based on canola containing event MS11 being approved for growing both in Australia and in other countries. Cultivation in Australia or New Zealand would require separate regulatory approval (see section 2.4.1.4).

Option 1 – Prepare a draft variation to Schedule 26

Consumers: Food containing event MS11 has been assessed as being as safe as food from conventional lines of canola.

Broader availability of imported canola products since, if MS11 is approved for commercial growing in other countries, there would be no restriction on imported foods containing this line.

For those MS11 food products containing novel DNA or novel protein, required labelling would allow consumers wishing to avoid these products to do so.

If MS11 is approved for commercial growing in either overseas countries or Australia it could be used in the manufacture of products using co-mingled canola seed. This means that there would be no cost involved in having to exclude MS11 seed from co-mingling and hence that there would be no consequential need to increase the prices of foods that are manufactured using co-mingled canola seed.

Government: Approval would avoid any conflict with WTO obligations. As mentioned above, food from MS11 has been assessed as being as safe as food from conventional lines of canola.

This option would be cost neutral in terms of compliance costs, as monitoring is required irrespective of whether or not a GM food is approved.

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.

Industry: Foods derived from MS11 would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of seed of MS11 from conventional canola seed, as for any GM crop, will be driven by industry, based on market preferences. Implicit in this will be a due regard to the cost of segregation.

Retailers may be able to offer a broader range of canola products or imported foods manufactured using canola derivatives.

There may be additional costs to the food industry as food ingredients derived from MS11 would require the 'genetically modified' labelling statement if they contain novel DNA or novel protein.

Option 2 – Reject application

Consumers: Possible restriction in the availability of imported canola products which may be produced after co-mingling of seed from MS11.

No effect on consumers wishing to avoid GM foods, as food from MS11 is not currently permitted in the food supply.

Potential increase in price of imported canola food products due to requirement for segregation of MS11 seed.

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 canola food products, if MS11 is commercialised overseas.

Without a food approval, it is unlikely a licence for the commercial growing of MS11 in Australia would be issued by the Gene Technology Regulator.

As food from MS11 has been found to be as safe as food from conventional lines of canola, not preparing a draft variation offers little benefit to consumers, as approval of MS11 by other countries could limit the availability of imported canola products in the Australian and New Zealand markets.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure varied as a result of Application A1140.

2.4.1.3 Any relevant New Zealand standards

Standard 1.5.2 and Schedule 26 apply in New Zealand.

2.4.1.4 Any other relevant matters

The Applicant has submitted applications for regulatory approval of MS11 to a number of other countries, as listed in Table 1.

The Applicant has stated they intend to apply for a licence to commercially grow line MS11 in Australia. This would require independent assessment and approval by the Office of the Gene Technology Regulator. Similarly if the Applicant wishes to grow MS11 in New Zealand, assessment must be undertaken by the Environmental Protection Authority in New Zealand.

Table 1: List of countries to whom applications for regulatory approval of MS11 have been submitted

Country	Agency	Type of approval sought	Status
USA	Department of Agriculture (USDA)	environment[1]/feed	Under assessment
	Food and Drug Administration (FDA)	food	Under assessment
Korea	Ministry of Food & Drug Safety (MFDS)	food	Under assessment
	Rural Development Administration	feed	Under assessment
Canada	Canadian Food Inspection Agency (CFIA)	environment[1]/feed	Under assessment
	Health Canada	food	Under assessment
EU	European Food Safety Authority	food	Under assessment
Taiwan	Taiwan Food and Drug Administration (TFDA)	food	Under assessment

[1]an authorisation for ‘environment’ indicates the line can be grown commercially in that country.

2.4.2. Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

Food derived from MS11 has been assessed based on the data requirements provided in the FSANZ *Application Handbook*[3] which, in turn reflect internationally-accepted GM food safety assessment guidelines. No public health and safety concerns were identified in this assessment. Based on the available evidence, including detailed studies provided by the Applicant, food derived from MS11 is considered as safe and wholesome as food derived from other commercial canola lines.

[3] http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx

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

In accordance with existing labelling provisions, food derived from MS11 would have to be labelled as ‘genetically modified’ if it contains novel DNA or novel protein (see Section 2.2.1).

2.4.2.3 The prevention of misleading or deceptive conduct

The provision of detection methodology by the Applicant (see Section 2.2.2) 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 Principles for the Risk Analysis of Foods derived from Biotechnology (Codex 2004). Based on these principles, the risk analysis undertaken for MS11 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 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. MS11 is a new food crop designed to provide a) canola breeders with a line that can be used in a hybrid breeding system that will confer increased vigour (and hence yields) and b) growers with an alternative broad spectrum herbicidal mode of action for canola farming systems.

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

Not applicable.

- **any written policy guidelines formulated by the Forum on Food Regulation**

No specific policy guidelines have been developed.

3 Draft variation

The draft variation to the Code is at Attachment A and 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 Legislation.

4 References

Codex (2004) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome. http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/

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 Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Food Standards (Application A1140 – Food derived from Herbicide-tolerant Canola Line MS11) 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 variation commences on the date specified in clause 3 of the 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 the above notice.

1 Name

This instrument is the *Food Standards (Application A1140 – Food derived from Herbicide-tolerant Canola line MS11) 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] **Schedule 26** is varied by inserting in the table to subsection S26—3(4) in alphabetical order under item 1

(f) herbicide-tolerant canola line MS11

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.

The Authority accepted Application A1140 which seeks permission for the sale and use of food derived from a genetically modified canola line, MS11, which has tolerance to glufosinate ammonium and is male sterile. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The variation inserts a permission for herbicide-tolerant canola line MS11 into Schedule 26 in order to permit the sale, or use in food, of food derived from that canola line.

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 A1140 will include one round of public consultation following an assessment and the preparation of a draft variation.

A Regulation Impact Statement was not required because the sale of food derived from MS11, 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] inserts paragraph (f) into item 1 of the table to subsection S26—3(4) in Schedule 26. The new paragraph refers to herbicide-tolerant canola line MS11. The effect of the variation is to permit the sale and use of food derived from that canola line in accordance with Standard 1.5.2.