

29 September 2017
[26-17]

Approval report – **Application A1140**

Food derived from Herbicide-tolerant Canola Line MS11

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Bayer CropScience Pty Ltd 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.

On 12 May 2017, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received nine submissions.

FSANZ approved the draft variation on 14 September 2017. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 28 September 2017.

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

Table of contents

EXECUTIVE SUMMARY.....	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD	3
1.4 REASONS FOR ACCEPTING THE APPLICATION	4
1.5 PROCEDURE FOR ASSESSMENT.....	4
1.6 DECISION.....	4
2 SUMMARY OF THE FINDINGS	4
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS.....	4
2.1.1 <i>General issues raised</i>	4
2.1.2 <i>Specific issues raised</i>	6
2.2 SAFETY ASSESSMENT.....	7
2.3 RISK MANAGEMENT.....	8
2.3.1 <i>Labelling</i>	8
2.3.2 <i>Detection methodology</i>	8
2.4 RISK COMMUNICATION	8
2.4.1 <i>Consultation</i>	8
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS.....	9
2.5.1 <i>Section 29</i>	9
2.5.2 <i>Subsection 18(1)</i>	11
3 REFERENCES.....	12
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	14
ATTACHMENT B – EXPLANATORY STATEMENT	16

Supporting document

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

SD1 Safety Assessment Report (at Approval)

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.

The FSANZ Board has approved the draft variation to Schedule 26 that includes 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 (PAT, Barnase and Barstar) has previously been assessed by FSANZ.

1.3 The current Standard

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 the 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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal. The approved draft variation is at Attachment A.

The related 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.

2 Summary of the findings

2.1 Summary of issues raised in submissions

2.1.1 General issues raised

A total of nine submissions were received of which six (all from New Zealand) were opposed to the proposed draft variation to Schedule 26.

Of the submissions received, some raised issues that are outside the scope of FSANZ's regulatory area e.g. ethnic concerns, economic considerations, environmental issues, farming practices, trade policy, and general GM issues not related to the MS11 application.

Responses to general safety issues raised or implied in the opposed submissions, are provided in Table 1. Specific issues are addressed in section 2.1.2.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
The systems and processes used to approve the application are deeply flawed and not fit for purpose	Auckland GE-free Coalition (AGEFC); GE Free Northland (GEFN); GE Free NZ (GEFNZ); Claire Bleakley	The approach used by FSANZ to assess the safety of GM food is based on core principles developed almost 20 years ago and published as guidelines by the Codex Alimentarius Commission (Codex 2003; Codex 2004). Over time, the assessment protocol has been the subject of scientific scrutiny but has proved to be a robust approach for whole food safety assessments. It is widely adopted and implemented around the world. While philosophical opposition to the technology remains, consumers can be confident that GM foods assessed under the protocol and approved for food use are as safe as their conventional counterparts.
Lack of animal feeding studies to address concerns about long term toxicity	AGEFC; GEFN; GEFNZ	<p>As indicated above, the approach used by FSANZ to assess the safety of GM foods is based on robust principles and guidelines that are accepted internationally and have withstood scientific scrutiny.</p> <p>There is general consensus among food regulators that the key focus in determining the safety of a GM food is the comparative compositional analysis. This concept was first considered and adopted in 1993 (OECD 1993) and there has not been any change to this approach (Herman et al. 2009).</p> <p>Compositional analysis and nutritional impact of food derived from the GM canola was considered in sections 4 and 5 of SD1. The conclusion from these sections was that seed from MS11 can be regarded as equivalent in composition to seed from conventional canola and is expected to have little nutritional impact.</p> <p>In 2007, FSANZ convened a workshop² to formally examine the usefulness of animal feeding studies to support the safety assessment of GM foods. The conclusion was that such studies do not contribute meaningful information on the long-term safety of a GM food, with the possible exception of a food in which the modification introduced a desired nutritional change. Therefore, for most GM foods, including those derived from MS11, feeding trials of any length are unlikely to contribute any further useful information to the safety assessment and are not warranted. There are also concerns about the unethical use of animals for feeding studies in the absence of any clearly identified compositional differences (Rigaud 2008; Bartholomaeus et al. 2013).</p>
There is no labelling of the oil to warn the vulnerable public of the dangers of GM-sourced canola	GEFNZ; Claire Bleakley;	<p>Only those GM foods assessed by FSANZ as safe are approved for sale. The labelling of approved GM foods is therefore not required for safety reasons.</p> <p>Specific labelling requirements are in Standard 1.5.2 and Schedule 26 and referenced in section 1.3 of this Report. Paragraph 1.5.2—4(1)(a) of Standard 1.5.2 exempts genetically modified food from labelling if it:</p> <ul style="list-style-type: none"> • has been highly refined where the effect of the refining process is to remove novel DNA or novel protein, and • is not listed in subsections S26—3(2) and (3) meaning it has no altered characteristics (e.g. a different nutritional profile). <p>In section 2.3.1 of this Report, FSANZ has provided likely labelling scenarios for possible products of MS11. Since the refined oil from MS11 is unlikely to contain novel DNA or protein, and it does not have altered characteristics, it would be indistinguishable from oil from non-GM canola.</p> <p>Further information on the labelling of GM foods³ can be found on the FSANZ website.</p>

² <http://www.foodstandards.gov.au/consumer/gmfood/Pages/roleofanimalfeedings3717.aspx>

³ <http://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx>

Issue	Raised by	FSANZ response
The safety of ingesting transgenes Horizontal gene transfer	GEFNZ	<p>DNA is a natural component of the human diet, being present to varying degrees in foods derived from plants and animals, especially those that have undergone minimal processing. There is no difference in terms of risk between recombinant DNA and the DNA already present in our diet.</p> <p>These issues has been considered in detail by FSANZ and a summary is available on the FSANZ website - http://www.foodstandards.gov.au/consumer/gmfood/recombinantdna/Pages/default.aspx</p>
Failure to address unintended effects using techniques such as whole genome sequencing and 'omics'	AGEFC; GEFN;	<p>The occurrence of unintended effects is not a phenomenon specific to genetic modification/transgenesis and, indeed, just as in conventional plant breeding programmes, extensive backcrossing is done in order to remove unintended effects. In both cases, those products with overt adverse phenotypic effects are easily detected and discarded during the generations that are produced prior to the selection of an elite product for regulatory assessment.</p> <p>The compositional analyses that are an integral part of the comparative approach to safety assessment of GM foods will highlight changes to key (targeted) compounds, noting that such changes may not necessarily be adverse and may not fall outside the range of biological variation. Experience in assessing over 70 GM food applications to FSANZ has shown that, to date, few compounds in the GM raw agricultural commodity, from which a food is produced, fall outside biological variation unless an intended effect is targeted (e.g. change to the fatty acid profile). Worldwide, and over many years, GM foods have been considered by other regulators, and entered the food supply without any plausible adverse effects being noted. GM foods are arguably the most analysed and characterised foods in the food supply.</p> <p>The above approach to safety assessment is known as a targeted approach. Non-targeted, profiling approaches, are largely covered by the generic term 'omics' and, as the name implies, notionally cover all molecules of biological importance. Genomics provides sequence information about the DNA and is approached using a number of different methods (e.g. Southern blots, PCR, Sanger sequencing, whole genome sequencing). The important feature of genomics is that the DNA is a fixed feature of an organism and therefore allows comparison over time and development. It cannot, however, definitively provide information on how that DNA is expressed and hence, cannot, of itself, always provide a measure of unintended effects. The other –omics e.g. transcriptomics, proteomics, metabolomics, miR-omics measure components that are subject to constant change (e.g. over time, location, environment, developmental stage) and hence can only provide a 'snapshot', which is meaningless in extrapolating to possible unintended effects without an enormous database of comparative information against which variation can be quantified. To date no such database exists.</p> <p>For some key papers discussing these issues see e.g. (Cellini et al. 2010; Chassy 2010; Riccroch 2013).</p>

2.1.2 Specific issues raised

2.1.2.1 *In two of the submissions, concerns were raised that total glucosinolates were significantly changed in MS11 and could cause severe reactions if eaten.*

Response

While the level of total glucosinolates in MS11 was significantly higher than in the control, this level was well within the range found: a) in the six non-GM reference lines planted alongside MS11; and b) reported in the published literature i.e. the increased level of total glucosinolates in MS11 is not biologically significant.

Irrespective of this, it is noted that while there may be glucosinolates present in the canola seed, there are essentially no glucosinolates present in the most widely used edible product of canola – its oil. During commercial canola processing, canola meal is the solid component by-product left after oil extraction. Due to the nature of the oil extraction process, close to 100% of the glucosinolates remain behind in the meal, and actually become slightly more concentrated (as a result of the removal of the oil component). The presence of glucosinolates in canola meal is one reason why the meal *per se* is not suitable for human consumption⁴ unless the anti-nutrients have been extracted. There is a standard (<30 µmol/g oil-free meal) for the maximum level of glucosinolates that can be present in canola meal (AOF 2015). Similarly, glucosinolates need to be removed from any protein isolate, produced for human consumption, from canola seed.

In the paper cited by GEFNZ⁵ it is stated that while there may be a carry-over of glucosinolates (from all sources not just canola meal) into livestock products used as food, the levels in these products are much lower than found in vegetables directly consumed by humans.

The widespread consumption of *Brassica* spp such as cabbage, kale, broccoli, turnip and radish, that are in the same family as canola, is of far greater significance regarding intake of glucosinolates than any products derived from canola seed.

2.2 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.

Minor typographical errors in the SD1 released with the call for submissions have been corrected.

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.

⁴ Note: the protein isolated from the meal does not contain glucosinolates and is promoted as a high quality protein source for human consumption

⁵ Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission on glucosinolates as undesirable substances in animal feed, *The EFSA Journal* (2008) 590, 1-76

2.3 Risk management

2.3.1 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 is listed in subsections S26—3(2) and (3) (such food 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.

2.3.2 Detection methodology

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee⁶ 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.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

Public submissions were invited on a draft variation which was released for public comment between 12 May and 23 June 2017. 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.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on this Application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of the safety assessment.

⁶ Now known as the Implementation Subcommittee for Food Regulation

Documents relating to Application A1140, including submissions received, are available on the [FSANZ website](#)⁷.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 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 cost/benefit analysis is 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 2.5.1.4).

Option 1 was selected.

Option 1 – Approve the 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.

⁷ <http://www.foodstandards.gov.au/code/applications/Pages/A1140GMCanolaMS11.aspx>

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 the draft variation to Schedule 26

As food derived from MS11 has been found to be as safe as food from conventional counterparts, not preparing a draft variation would offer little relative benefit to consumers, government and industry.

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

Standard 1.5.2 and Schedule 26 also apply in New Zealand.

2.5.1.4 Any other relevant matters

The Applicant has submitted applications for regulatory approval of MS11 to a number of other countries, as listed in Table 2.

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 2: 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
	Council of Agriculture (COA)	feed	Under assessment

¹an authorisation for 'environment' indicates the line can be grown commercially in that country.

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

Food derived from MS11 has been assessed based on the data requirements provided in the FSANZ [Application Handbook](#)⁸ 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.

2.5.2.2 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 2.3.1).

2.5.2.3 The prevention of misleading or deceptive conduct

The provision of sequence information by the Applicant will permit the detection of food derived from MS11 (see section 2.3.2).

⁸ <http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

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 to improve yield, and b) growers with an alternative broad spectrum herbicidal mode of action for canola farming systems.

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

Issues, related to consumer information and safety, are considered in Section 2.2 and 2.3 above.

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

No specific policy guidelines have been developed by the Forum on Food Regulation.

3 References

AOF (2015) Section 1: quality standards, technical information & typical analysis 2015/16. Australian Oilseeds Federation Incorporated.
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Ricroch AE (2013) Assessment of GE food safety using '-omics' techniques and long-term animal feeding studies. *New Biotechnology* 30(4):349–354

Rigaud N (2008) Biotechnology: ethical and social debates. OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda".
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Attachments

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

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



Food Standards (Application A1140 – Food derived from Herbicide-tolerant Canola Line MS11) 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 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 – 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.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a variation to insert an entry for herbicide-tolerant canola line MS11 into the table to subsection S26—3(4) in Schedule 26 in order to permit the sale, or use in food, of food derived from that canola line in accordance with Standard 1.5.2.

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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 12 May 2017 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 26 is likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

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

6. Variation

Item [1] inserts new 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.