

**18 January 2021**  
**[147–21]**

## **Call for submissions – Application A1216**

### **Food derived from herbicide-tolerant canola line MON94100**

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Bayer CropScience Proprietary Limited seeking to permit the sale and use of food derived from a food produced using gene technology: canola line MON94100. This canola line has been genetically modified for tolerance to the herbicide dicamba. A draft food regulatory measure has been prepared. 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 variation.

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 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 to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

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

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 1 March 2021**

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

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

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

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### Supporting documents

The [following documents](#)<sup>1</sup> which informed the assessment of this application are available on the FSANZ website:

- SD1 Safety Assessment Report
- SD2 Safety assessment supplement

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<sup>1</sup> <https://www.foodstandards.gov.au/code/applications/Pages/A1216.aspx>

## Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Bayer CropScience Proprietary Limited to request a variation to Schedule 26 in the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): canola line MON94100. Canola line MON94100 has been genetically modified for tolerance to the herbicide dicamba.

This application has been accepted for assessment under a pilot project between FSANZ and the Food Directorate of Health Canada for the joint preparation and sharing of safety assessments for GM foods – referred to as safety assessment sharing.

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 canola line MON94100 is in Supporting Documents 1 and 2. No potential public health and safety concerns have been identified. Based on the data provided and other information, food derived from canola line MON94100 is considered to be as safe for human consumption as food derived from conventional non-GM canola cultivars. Existing labelling requirements for GM food will apply to food derived from canola line MON94100 in accordance with the Code.

FSANZ has decided to prepare a draft variation to amend Schedule 26 of the Code to include a reference to 'herbicide-tolerant canola line MON94100' in the table to subsection S26—3(4). The effect of the draft variation will be to permit the use or sale of food derived from this canola line in accordance with the Code.

# 1 Introduction

## 1.1 The applicant

Bayer CropScience Proprietary Limited is a technology provider to a number of sectors including the agriculture sector.

## 1.2 The application

Application A1216 was submitted on 13 October 2020. It seeks approval for the sale and use of food derived from canola line MON94100 that has tolerance to the herbicide dicamba (3,6-dichloro-2-methoxybenzoic acid).

Tolerance to dicamba is achieved through expression of the *dicamba mono-oxygenase (dmo)* gene derived from the bacterium *Stenotrophomonas maltophilia*. The encoded protein, dicamba mono-oxygenase (DMO), has been assessed previously by FSANZ.

Food derived from canola line MON94100 may enter the Australian and New Zealand food supply as imported food products. Oil from canola lines containing the MON94100 event would be the primary food product. Other foods derived from MON94100 including canola meal or seeds may also potentially enter the food supply. Unprocessed viable canola seeds would be considered a genetically modified organism and would not be permitted in Australia and New Zealand without prior assessment and approval by the Gene Technology Regulator in Australia and the Environmental Protection Authority (EPA) in New Zealand.

### 1.2.1 Safety assessment sharing pilot with Health Canada

The application was submitted for assessment under a pilot project being conducted by FSANZ and the Food Directorate of Health Canada for the joint preparation and sharing of safety assessments for food produced using gene technology (GM food)<sup>2</sup> – referred to as safety assessment sharing.

The pilot is the result of a collaboration between FSANZ and Health Canada that commenced in 2013 and which builds on a long history of information sharing and cooperation at an international level on GM foods. The purpose of the collaboration was to explore opportunities for improving the efficiency of GM food safety assessment by streamlining the assessment process. The goal of safety assessment sharing is to establish a system where a safety assessment is jointly prepared that meets the separate requirements of both agencies when each undertaking their own separate and independent assessments.

Extensive work undertaken in the early stages of the collaboration confirmed the compatibility of FSANZ's and Health Canada's safety assessment approaches, both in terms of how safety assessments are conducted and the conclusions that are reached. Both agencies also adhere to internationally agreed principles and guidelines for the conduct of GM food safety assessment which were developed by the Codex *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology (Codex, 2009). This provides a strong basis for safety assessment sharing between the two agencies.

Under the system, where GM food approval is being sought in Canada, Australia and New Zealand, an applicant may request their application be assessed using a safety assessment sharing approach. Applications must be submitted to both agencies and assessed separately by each agency according to each agency's requirements, but only one documented food

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<sup>2</sup> <https://www.foodstandards.gov.au/science/international/Pages/gm-food-safety.aspx>

safety assessment is jointly prepared by both agencies. For canola line MON94100, the joint food safety assessment was initially prepared by Health Canada and then provided to FSANZ for FSANZ's review and confirmation that it met all relevant requirements for Australian and New Zealand purposes. Following confirmation that these requirements were met, the jointly prepared safety assessment was used as part of the FSANZ risk analysis, as detailed in this call for submissions.

### 1.3 The current standard

Pre-market approval is necessary before a GM food can enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment. Standard 1.5.2 sets out the permission and conditions for the sale of food that consists of, or has as an ingredient, a GM food. Foods that have been assessed and approved are listed in Schedule 26 of the Australia New Zealand Food Standards Code (the Code).

Subject to certain exceptions listed below, section 1.5.2—4 requires food to be labelled as 'genetically modified' where novel DNA and/or novel protein remains present in the final food. The requirement applies to foods for sale that consist of, or have as an ingredient (including food additives and processing aids), food that is a *genetically modified food*<sup>3</sup>. Standard 1.2.1 provides that the requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer - see subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

Foods listed in subsections S26—3(2), (2A) and (3) of Schedule 26 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. Foods listed in these subsections 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.

The labelling requirement in section 1.5.2—4 does not apply if the genetically modified food:

- has been highly refined (other than food that has been altered), where the effect of the refining process is to remove novel DNA or novel protein; or
- is a substance used as a processing aid or a food additive, where novel DNA or novel protein from the substance does not remain present in the final food; or
- is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%); or
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient.

The above labelling requirement also does not apply if the food for sale is intended for immediate consumption, and is prepared and sold from food premises and vending machines, including restaurants, take away outlets, caterers, or self-catering institutions.

If the GM food for sale is not required to bear a label, the labelling information in section 1.5.2—4 must accompany the food or be displayed in connection with the display of the food (in accordance with subsections 1.2.1—9(2) and (3) of Standard 1.2.1).

Subsection 1.1.1—10(8) of Standard 1.1.1 states that food for sale must comply with all

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<sup>3</sup> Section 1.5.2—4(5) defines **genetically modified food** to mean a \*food produced using gene technology that

- a) contains novel DNA or novel protein; or
- b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section (*that being section 1.5.2—4*).

relevant labelling requirements imposed by the Code for that food.

## 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 *Food Standards Australia New Zealand Act 1991* (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

### 2.1.1 Safety assessment sharing process

A food safety assessment of canola line MON94100 (Supporting Document 1) was initially undertaken by the Food Directorate of Health Canada, according to their *Guidelines for the Safety Assessment of Novel Foods*<sup>4</sup> and using data submitted to them by Bayer CropScience on behalf of Monsanto Canada ULC as part of an application to Health Canada for novel food approval. Before being finalised by Health Canada, the safety assessment was reviewed by FSANZ to ensure it met all relevant requirements for Australian and New Zealand purposes.

The jointly prepared safety assessment and document was then used by both agencies in each making their own separate and independent safety assessments of canola line MON94100.

While Health Canada's *Guidelines for the Safety Assessment of Novel Foods*, and data requirements for GM foods, are broadly similar to the FSANZ guidelines and data requirements, some differences exist. These differences were addressed by FSANZ as follows:

- Information about the history of use of canola – the Health Canada assessment provides information about the history of use of canola in Canada. Additional information that is specific to Australia and New Zealand is provided in Supporting Document 2 (SD2).
- Information about the stability of the herbicide tolerance trait in MON94100 - Health Canada requires information on either genetic or phenotypic stability of the trait but not both. For MON94100, Bayer CropScience provided evidence of genetic stability to Health Canada. In their application to FSANZ, Bayer CropScience provided evidence of both genetic and phenotypic stability in accordance with Guideline 3.5.1 of the FSANZ *Application Handbook*<sup>5</sup>. FSANZ's assessment of the additional phenotypic stability information is provided in SD2.

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<sup>4</sup> <https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/safety.html>

<sup>5</sup> <https://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

- Information about novel herbicide metabolites – in Canada, the review of herbicide metabolites is the responsibility of Health Canada’s Pest Management Regulatory Agency, not the Food Directorate. This aspect was therefore not addressed in the Health Canada safety assessment. In the application to FSANZ, Bayer CropScience submitted information about dicamba metabolites in accordance with Guideline 3.5.1 of the FSANZ *Application Handbook*. FSANZ’s assessment of this information is provided in SD2.

### **2.1.2 Safety assessment summary**

The safety assessment of canola line MON94100 included the following key elements:

- a characterisation of the transferred genetic material, its origin, function and stability in the canola genome
- characterisation of novel nucleic acids and protein in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes
- the potential for any newly expressed protein to be either allergenic or toxic in humans.

The safety assessment had regard to information from a variety of sources including, but not limited to, a data package provided by the applicant (application and study reports), the scientific literature and previous applications.

The assessment of canola line MON94100 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 canola line MON94100, or any risks to animals that may consume feed derived from canola line MON94100. Cultivation in Australia or New Zealand would require separate regulatory assessment and approval, by the Gene Technology Regulator in Australia and by the EPA in New Zealand.

No potential public health and safety concerns were identified.

Based on the data submitted in support of the application, and other available information, food derived from canola line MON94100 is considered to be as safe for human consumption as food derived from non-GM canola cultivars.

## **2.2 Risk management**

### **2.2.1 Labelling**

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food for sale derived from canola line MON94100 would be required to be labelled as ‘genetically modified’ if (among other things) the GM food:

- contains novel DNA or novel protein; or
- is listed in subsection S26—3(2), 2(A) or (3) of Schedule 26 as being subject to the condition that the labelling must comply with section 1.5.2—4 of Standard 1.5.2 (such food has altered characteristics). FSANZ has determined that food derived from MON94100 does not have altered characteristics.

As noted in section 1.2 of this report, oil would be the major product from canola line MON94100. Canola oil is unlikely to contain novel DNA or novel protein due to the refining process used to extract the oil from the seed. In accordance with the existing labelling provisions in Standard 1.5.2, labelling is unlikely to apply to highly refined products from

canola line MON94100 such as oil. MON94100 products such as whole canola seeds<sup>6</sup> and canola meal (a by-product of seed oil extraction) will contain novel DNA and novel protein, and will require labelling as 'genetically modified'.

The requirements for labelling as 'genetically modified' differ depending on whether the GM food is an ingredient of the food for sale or not. For example, bread containing whole canola seeds that is for retail sale would require the labelling statement.

However, FSANZ notes that MON94100 products may be used to manufacture a food that is not itself a food for sale, but is used as an ingredient in foods for retail sale or in a food sold to a caterer (for example, whole canola seeds from MON94100 are used as an ingredient in bread and the bread is then used as a croutons in a 'ready meal' salad). As such, the ingredients in the food for sale are not GM foods and are not subject to labelling requirements set out in section 1.5.2—4.

## **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<sup>7</sup> to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food produced using 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 A1216.

## **2.3 Risk communication**

### **2.3.1 Consultation**

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

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

As this is the first GM food application under the safety assessment sharing arrangement, FSANZ has provided additional information on our website<sup>8</sup> about the assessment process.

The draft variation will be considered for approval by the FSANZ Board taking into account all 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.

### **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

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<sup>6</sup> Unprocessed viable canola seeds would require other approvals before they can be sold in Australia and New Zealand (refer to section 1.2).

<sup>7</sup> Now known as the Implementation Subcommittee for Food Regulation.

<sup>8</sup> <https://www.foodstandards.gov.au/science/international/Pages/gm-food-safety.aspx>

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 canola line MON94100 is unlikely to have a significant effect on international trade. 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) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as varying Schedule 26 is a consequential change of maintaining a permitted schedule of GM foods. Additionally, permitting a new GM food is deregulatory as using the gene technology will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application). This analysis considers permitting the sale and use of food derived from canola line MON94100.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the sale and use of food derived from canola line MON94100.

#### *Costs and benefits of permitting the sale and use of food derived from canola line MON94100*

The sale of foods derived from canola line MON94100 would be permitted under the Code, allowing broader market access and increased choice in raw materials. For those food products containing novel DNA or novel protein from MON94100, labelling is required to assist consumers wishing to avoid these products to do so.

Due to the voluntary nature of the permission, manufacturers and retailers would only engage with foods derived from canola line MON94100, where they believe a net benefit exists for them. Part of any cost savings to industry may be passed onto consumers.

There may be small and likely inconsequential costs of monitoring an extra GM food ingredient for regulators to ensure compliance with labelling requirements.

*Conclusions from cost benefit considerations*

FSANZ’s assessment is that the direct and indirect benefits that would arise from permitting the sale and use of food derived from canola line MON94100, most likely outweigh the associated costs.

**2.4.1.2 Other measures**

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than varying Schedule 26 as a result of application A1216.

**2.4.1.3 Any relevant New Zealand standards**

Standard 1.5.2 and Schedule 26 apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

**2.4.1.4 Any other relevant matters**

The applicant has submitted applications for regulatory approval of canola line MON94100 to other countries, as listed in Table 1.

Cultivation in Australia or New Zealand would require independent assessment and approval by the Gene Technology Regulator and NZ EPA, respectively.

**Table 1: List of countries to whom applications for regulatory approval of MON94100 have been submitted**

Country	Agency	Type of approval sought	Status
Canada	CFIA	Environmental release & feed	Submitted
	Health Canada	Food	Submitted

Further other relevant matters are considered below.

**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**

FSANZ’s assessment did not identify any public health and safety concerns with food derived from canola line MON94100. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ’s assessment is that food derived from canola line MON94100 is as safe as food derived from other non-GM canola lines.

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

Existing labelling requirements for GM food will apply to food derived from canola line MON94100 in accordance with the Code to enable informed consumer choice (see Section 2.2.1).

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

The provision of DNA sequence information by the applicant (as described in Section 2.2.2) satisfies this objective.

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

FSANZ has also had regard to:

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

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2009). Based on these principles, the risk analysis undertaken for canola line MON94100 used the best scientific evidence available, including the jointly prepared safety assessment. The applicant submitted 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 producing foods. Canola line MON94100 is a new food crop designed to provide growers with an additional herbicide-tolerance option for canola farming systems.

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

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

- **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 the date of 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 (2009) Foods derived from modern biotechnology, Second Edition. Codex Alimentarius Commission, Rome. <http://www.fao.org/3/a1554e/a1554e00.htm>

## **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 A1216 – Food derived from herbicide-tolerant canola line MON94100) 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 the delegate]

Scott Crerar  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

**1 Name**

This instrument is the *Food Standards (Application A1216 – Food derived from herbicide-tolerant canola line MON94100) 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

(h) herbicide-tolerant canola line MON94100

## **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 A1216 which seeks to permit the sale and use of food derived from canola line MON94100 as a new food produced using gene technology (a GM food). Canola line MON94100 has been genetically modified for tolerance to the herbicide, dicamba. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

### **2. Purpose**

The purpose of the draft variation is to permit the sale and use of food derived from genetically modified canola line MON94100.

### **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 A1216 will include one round of public consultation following an assessment and the preparation of a draft variation. A call for submissions (including the draft variation) will occur for a six-week consultation period.

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 GM foods (ref 12065). This standing exemption was provided as varying Schedule 26 is a consequential change of maintaining a permitted schedule of GM foods. Additionally, permitting a new GM food is deregulatory as using the food will be voluntary if the Application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

### **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] amends Schedule 26 by inserting new paragraph (h) into item 1 of the table to subsection S26—3(4) in Schedule 26 in alphabetical order.

The new paragraph refers to herbicide-tolerant canola line MON94100.

Canola line MON94100 has been genetically modified for tolerance to the herbicide, dicamba.

The effect of the variation is to permit the sale and use of food derived from that canola line in accordance with the Code.