12 May 2021
155-21

Approval report – Application A1216

Food derived from herbicide-tolerant canola line MON94100

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

On 18 January 2021, FSANZ sought submissions on a draft variation to Schedule 26 of the Australia New Zealand Food Standards Code and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 28 April 2021. The Food Ministers' Meeting (formerly the Australia and New Zealand Ministerial Forum on Food Regulation) was notified of FSANZ's decision on 12 May 2021.

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

Supporting documents

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

SD1 Safety Assessment Report
SD2 Safety assessment supplement

[1] 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 canola line MON94100, a new food produced using gene technology (GM food). Canola line MON94100 has been genetically modified for tolerance to the herbicide dicamba.

This application was accepted for assessment under a project between FSANZ and the Food Directorate of Health Canada. The project is implementing the joint preparation and sharing of safety assessments for GM foods.

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.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 18 January 2021. Three submissions were received, all of which supported the draft variation.

For the reasons summarised in this report, FSANZ has decided to approve the draft variation proposed following assessment without change. The draft variation amends Schedule 26 of the Code by inserting a reference to ‘herbicide-tolerant canola line MON94100’ in the table to subsection S26—3(4). The effect of the draft variation is to permit the use and 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 *d*icamba *m*ono-*o*xygenase (*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 line MON94100 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 project with Health Canada

The application was submitted for assessment under a project being conducted by Food Standards Australia New Zealand (FSANZ) and the Food Directorate of Health Canada to implement the joint preparation and sharing of safety assessments for food produced using gene technology (GM food)[2] – referred to as safety assessment sharing.

The project 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

[2] https://www.foodstandards.gov.au/science/international/Pages/gm-food-safety.aspx

by each agency according to each agency's requirements, but only one documented food 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 assessment.

1.3 The current standard

Pre-market approval is necessary before a food produced using gene technology (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*[3]. 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).

[3] 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*).

Subsection 1.1.1—10(8) of Standard 1.1.1 states that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

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 *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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved without change. The approved draft variation takes effect on the date of 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 assessment

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 18 January 2021 for a six week consultation period. Three submissions were received, all from government agencies. All three submissions supported the draft variation and did not raise any issues.

2.2 Safety assessment

2.2.1 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*[4] 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

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

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*[5]. FSANZ's assessment of the additional phenotypic stability information is provided in SD2.

- 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.

2.2.2 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. The assessment therefore did not address any risks to the environment that may occur as a 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.

[5] https://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx

2.3 Risk management

2.3.1 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food for sale derived from a GM food such as canola line MON94100 will 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 will 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[6] 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 will 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.

2.3.2 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-Committee[7] 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.

2.4 Risk communication

2.4.1 Consultation

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

[6] Unprocessed viable canola seeds would require other approvals before they can be sold in Australia and New Zealand (refer to section 1.2).
[7] Now known as the Implementation Subcommittee for Food Regulation.

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

As this was the first GM food application under the joint safety assessment sharing arrangement, FSANZ has provided additional information on the website[8] about the assessment process.

Public submissions were invited on a draft variation which was released for public comment between 18 January and 1 March 2021. 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 FSANZ. All comments are valued and contribute to the rigour of FSANZ's assessment.

Documents relating to Application A1216, including submissions received, are available on the FSANZ website[9].

2.4.2 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 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.

2.5 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.

2.5.1 Section 29

2.5.1.1 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

[8] https://www.foodstandards.gov.au/science/international/Pages/gm-food-safety.aspx
[9] https://www.foodstandards.gov.au/code/applications/Pages/A1216.aspx

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. A consideration of costs and benefits was included in the call for submissions (CFS) report based on the information and data held at that time. No further information has been received in the consultation process that influenced the findings from the analysis of costs and benefits in the CFS.

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.

2.5.1.2 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.

2.5.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.5.1.4 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	Approved
	Health Canada	Food	Approved

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

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.

2.5.2.2 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 2.3.1).

2.5.2.3 The prevention of misleading or deceptive conduct

The provision of DNA sequence information by the applicant (as described in Section 2.3.2) satisfies 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 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**

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 Food Ministers' Meeting[10]**

No specific policy guidelines have been developed.

3 Draft variation

The approved draft variation to the Code is at Attachment A and is intended to take effect on the date of gazettal.

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

[10] Formerly known as the Australia and New Zealand Ministerial Forum on Food Regulation

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

Food Standards (Application A1216 – Food derived from herbicide-tolerant canola line MON94100) 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 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 – 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 a draft variation.

Following consideration by the Food Ministers' Meeting (formerly the Australia and New Zealand Ministerial Forum on Food Regulation)[11], 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 sunsetting under the Legislation Act 2003.

2. Purpose

The purpose of the draft variation is to permit the sale and use of food derived from a new GM food: canola line MON94100 which has been genetically modified for tolerance to the herbicide, dicamba.

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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report.

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.

[11] The Forum name change took effect on 21 February 2021 following a decision by Ministers.

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.