

25 September 2023
263-23

Call for submissions – Application A1274

Food derived from disease-resistant banana line QCAV-4

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Queensland University of Technology (QUT) seeking to amend the Australia New Zealand Food Standards Code to permit the sale and use of food derived from a new food produced using gene technology: banana line QCAV-4. This banana line has been genetically modified for resistance to the fungal disease *Fusarium wilt tropical race 4 (TR4)*, also known as Panama disease. A draft 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 food regulatory measure.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

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](#).

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made by emailing your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 6 November 2023

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 a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	4
1.1 THE APPLICANT	4
1.2 THE APPLICATION.....	4
1.3 THE CURRENT STANDARD	4
1.4 REASONS FOR ACCEPTING APPLICATION	5
1.5 PROCEDURE FOR ASSESSMENT	5
2 SUMMARY OF THE ASSESSMENT	5
2.1 RISK ASSESSMENT	5
2.2 RISK MANAGEMENT	6
2.2.1 <i>Regulatory approval</i>	6
2.2.2 <i>Labelling</i>	7
2.2.3 <i>Detection methodology</i>	7
2.3 RISK COMMUNICATION.....	8
2.3.1 <i>Consultation</i>	8
2.3.2 <i>World Trade Organization (WTO)</i>	8
2.4 FSANZ ACT ASSESSMENT REQUIREMENTS	8
2.4.1 <i>Section 29</i>	8
2.4.2 <i>Subsection 18(1)</i>	9
2.4.3 <i>Subsection 18(2) considerations</i>	10
3 DRAFT VARIATION	11
4 REFERENCES	11
ATTACHMENT A – DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	12
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT.....	14

Supporting document

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

SD1 Safety Assessment Report

¹<https://www.foodstandards.gov.au/code/applications/Pages/A1274---Food-derived-from-disease-resistant-banana-line-QCAV-4-.aspx>

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Queensland University of Technology 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): banana line QCAV-4. Banana line QCAV-4 has been genetically modified to have resistance to the fungal disease Fusarium wilt tropical race 4 (TR4), also known as Panama disease.

A safety assessment is a critical part of the assessment approval process for all GM food applications. The completed safety assessment is in Supporting Document 1 (SD1). The safety assessment of banana line QCAV-4 found no potential public health and safety concerns. Based on the data provided and other information, food derived from banana line QCAV-4 is considered to be as safe for human consumption as food derived from non-GM banana cultivars.

The applicant is also seeking approval from the Gene Technology Regulator (GTR) for commercial cultivation of banana line QCAV-4 in Australia. This requires a separate regulatory assessment which is being undertaken by the Office of the GTR (OGTR). If approved by the GTR, banana line QCAV-4 may be cultivated in Australia and, subject to approval of the draft variation, food derived from banana line QCAV-4 may be sold in Australia or New Zealand primarily as fresh fruit or as processed products.

The applicant has stated that Australia's banana industry mainly serves the domestic market, therefore fresh fruit derived from the GM banana is unlikely to be exported and sold in New Zealand if approved to be cultivated in Australia. However, some processed products may be sold in New Zealand. Food businesses intending to export / import fresh GM banana to / into New Zealand will need to consult the New Zealand Environmental Protection Authority (EPA) about whether the fresh banana fruit would be considered a new organism. Food businesses should also seek advice from the New Zealand Ministry for Primary Industries (MPI) in relation to biosecurity requirements. Cultivation of banana line QCAV-4 in New Zealand would require an independent assessment and approval from EPA.

Existing labelling requirements for GM food would apply to food derived from banana line QCAV-4 in accordance with the Code.

For reasons set out above and in the assessment summary, FSANZ has decided to prepare a draft variation to amend Schedule 26 and Standard 1.2.1 of the Code. The draft variation would amend Schedule 26 by including a new item 11 in the table to subsection S26—3(4), which would comprise of 'Banana' as the commodity and an associated reference to 'disease-resistant banana line QCAV-4' to permit the sale and use of food derived from that banana line. As a consequence of that amendment, the draft variation would also amend Standard 1.2.1 of the Code by including new paragraph (ba) in subsection 1.2.1—9(3). New paragraph (ba) would effectively require information about GM food to be provided in accordance with sections 1.5.2—4 and 1.2.1—9 where whole or cut fresh fruit and vegetables (other than seed sprouts or similar products), e.g. fresh whole and cut bananas from this banana line, are sold in a package that does not obscure the nature or quality of the food.

If approved, the effects of the draft variation would be:

- to permit the sale and use of food derived from this banana line in accordance with the Code; and
- to require that information about GM food be provided in accordance with sections 1.5.2—4 and 1.2.1—9 where whole or cut fresh fruit and vegetables (other than seed

sprouts or similar products), e.g. fresh whole and cut bananas from this banana line, are sold in a package that does not obscure the nature or quality of the food.

FSANZ seeks submissions on the draft variation.

1 Introduction

1.1 The Applicant

Queensland University of Technology is a higher education institution in Australia with expanding research output in technology and innovation.

1.2 The Application

Application A1274 was submitted on 11 April 2023. It seeks an amendment to 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): banana line QCAV-4. Banana line QCAV-4 has been genetically modified for resistance to the fungal disease Fusarium wilt tropical race 4 (TR4), also known as Panama disease.

Disease resistance is conferred by the expression of the novel plant resistance protein (R-protein) MamRGA2, encoded by the *MamRGA2* gene from wild banana, *Musa acuminata* ssp. *malaccensis*. The MamRGA2 protein allows the banana plant to detect the presence of the infecting fungus, which triggers the plant's defence response preventing further infection by the fungus. FSANZ has not previously assessed the MamRGA2 protein.

Banana line QCAV-4 also contains a commonly used antibiotic resistance marker gene *nptII* from the ubiquitous gut bacterium *Escherichia coli*. *nptII* encodes the neomycin phosphotransferase type II protein (NPTII) and confers resistance to the antibiotics neomycin and kanamycin. FSANZ has assessed the NPTII protein in previous applications.

The applicant is currently seeking a licence for the commercial cultivation of banana line QCAV-4 from the Gene Technology Regulator (GTR)². This requires a separate regulatory assessment which is being undertaken by the Office of the GTR (OGTR). If approved by the GTR, banana line QCAV-4 may be cultivated in Australia and subject to approval of the draft variation, food derived from banana line QCAV-4 may be sold in Australia or New Zealand primarily as fresh fruit or as processed products.

The applicant has stated that Australia's banana industry mainly serves the domestic market, therefore fresh fruit derived from the GM banana is unlikely to be exported and sold in New Zealand if approved to be cultivated in Australia. However, some processed products may be sold in New Zealand. Food businesses intending to export / import fresh GM banana to / into New Zealand will need to consult with the New Zealand Environmental Protection Authority (EPA)³ about whether the fresh banana fruit would be considered a new organism. Food businesses should also seek advice from the New Zealand Ministry for Primary Industries (MPI)⁴ in relation to biosecurity requirements. Cultivation of banana line QCAV-4 in New Zealand would require an independent assessment and approval from EPA.

1.3 The current standard

Pre-market approval is necessary before GM foods 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 of the Code sets out the permission and conditions for sale of food that consists of, or has as an ingredient, a GM food. Foods that have been assessed

² The Office of the Gene Technology Regulator (OGTR) provides administrative support to the Gene Technology Regulator in the performance of functions under the *Gene Technology Act 2000*

³ The EPA implements and enforces the *Hazardous Substances and New Organisms (HSNO) Act 1996*. Email: NewOrganisms@epa.govt.nz

⁴ <https://www.mpi.govt.nz/>

and approved are listed in Schedule 26 of the Code.

Subject to the exceptions listed below, section 1.5.2—4 requires food to be labelled as 'genetically modified' where novel DNA and/or novel protein is present in the food for sale.

Additionally, foods listed in subsections S26—3(2), (2A) and (3) of 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. These foods 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.

The requirement to label as 'genetically modified' 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*⁵. The requirements imposed by section 1.5.2—4 apply to foods for sale and to foods sold to a caterer in accordance with Standard 1.2.1 (see subsection 1.2.1—8(1) and section 1.2.1—15 respectively).

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

If the food for sale is a food not required to bear a label and is not in a package, 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 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 1991* (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

The safety assessment of banana line QCAV-4 is provided in Supporting Document 1 (SD1)

⁵ Subsection 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*).

and included the following key elements:

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

In conducting the safety assessment, FSANZ 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 other applications.

The assessment of banana line QCAV-4 was restricted to human food safety and nutritional issues.

The applicant is currently seeking a licence from the GTR for the commercial cultivation of banana line QCAV-4 in Australia. Risks to the environment that may occur as the result of growing banana line QCAV-4, or any risks to animals that may consume feed derived from banana line QCAV-4, will be considered by the OGTR as part of their assessment process.

No potential public health and safety concerns have been identified.

Based on the data provided in the present application and other available information, food derived from banana line QCAV-4 is considered to be as safe for human consumption as food derived from non-GM banana cultivars.

2.2 Risk management

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation to the Code.

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code which, if approved would:

- permit the sale and use of food derived from banana line QCAV-4 in accordance with the Code; and
- require that information about GM food be provided in accordance with sections 1.5.2—4 and 1.2.1—9 where whole or cut fresh fruit and vegetables (other than seed sprouts or similar products), e.g. fresh whole and cut bananas from this banana line, are sold in a package that does not obscure the nature or quality of the food.

2.2.1 Regulatory approval

Banana line QCAV-4 is a GM food for Code purposes as it is developed from ‘an organism which has been modified using gene technology’. FSANZ is proposing to list banana line QCAV-4 in the table to subsection S26—3(4) (see item [2] of the draft variation in Attachment A). If approved, the proposed amendment would provide permission for the sale and use of food derived from banana line QCAV-4 as a GM food in accordance with the Code.

2.2.2 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 banana line QCAV-4, 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 banana line QCAV-4 does not have altered characteristics (see sections 5 and 6 of SD1).

Fresh banana, including its peel, and processed foods from banana line QCAV-4, such as dried or frozen banana and banana pulp, would contain novel DNA or novel protein and would require labelling as 'genetically modified'.

The label statement 'genetically modified' must be made in conjunction with the name of the GM food (subsection 1.5.2—4(2)). If the GM food is present in the food for sale as an ingredient, this statement may be included in the statement of ingredients (subsection 1.5.2—4(3)).

Unpackaged fresh, whole bananas would be subject to information requirements for food for sale that is not required to bear a label (section 1.2.1—9). In accordance with subsection 1.2.1—9(2) and paragraph 1.2.1—9(3)(b), the label statement 'genetically modified' must be stated in labelling that accompanies the food or is displayed in connection with the display of the food.

Whole or cut fresh fruit and vegetables (other than seed sprouts or similar products) sold in a package that does not obscure the nature or quality of the food (referred to in paragraph 1.2.1—6(1)(c)) do not have to bear a label under section 1.2.1—6. Consequently, information requirements in section 1.2.1—9 apply to such food.

However, FSANZ notes the information requirements in section 1.2.1—9 about GM food apply only if the food for sale is not in a package (see paragraph 1.2.1—9(3)(b)). As such, this provision does not capture the intent of providing information about GM food in accordance with section 1.5.2—4 when the food for sale is food referred to in paragraph 1.2.1—6(1)(c) i.e. whole or cut fresh fruit and vegetables (other than seed sprouts or similar products) (in this case, whole or cut fresh bananas from banana line QCAV-4), which is sold in a package that does not obscure the nature or quality of the food.

FSANZ is therefore proposing the draft variation also includes an amendment of subsection 1.2.1—9(3) so that information about GM food (including, if approved, whole or cut fresh bananas from banana line QCAV-4) would have to be provided in accordance with sections 1.5.2—4 and 1.2.1—9 for a food referred to in paragraph 1.2.1—6(1)(c) (see item [1] of the draft variation in Attachment A).

2.2.3 Detection methodology

An Expert Advisory Group (EAG) comprising laboratory personnel and representatives of 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

⁶ Now known as the Implementation Subcommittee for Food Regulation.

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 PCR⁷-based detection method. This sequence information was supplied by the applicant for A1274.

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, FSANZ's social media channels and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on draft variation.

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 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 banana line QCAV-4 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 Impact Analysis (OIA) has previously advised that a Regulatory Impact Statement (RIS) is not required for any application that permits the sale of GM food.

⁷ Polymerase Chain Reaction.

However, to meet FSANZ Act requirements, FSANZ has given consideration to the costs and benefits that may arise from the variation to the Code proposed by the application.

In FSANZ's view, the likely benefits of the variation to the Code (as a result of approving the draft variation) outweigh the likely costs.

The food industry may benefit from this application being approved. Permitting the sale and use of food derived from banana line QCAV-4 will reduce the risk posed to banana growers by the TR4 disease. If the applicant makes banana line QCAV-4 available to growers, growing the line is voluntary and therefore growers within the industry will use the variation where a commercial net benefit exists for them.

There is not expected to be any significant costs to consumers. As discussed in this call for submissions, consumers will be informed that this variety of bananas are genetically modified. Therefore consumers will have a choice to consume or not consume the product. In addition, this application demonstrates that the GM banana line is safe to consume.

Consumers will benefit if the risk of TR4 becoming widespread materialises. Data indicates that bananas are the highest selling fruit in Australia. Approval of this banana line will allow this demand to continue to be met if current crops are destroyed by the TR4 disease.

There is not expected to be any significant costs or impacts for governments.

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

The applicant has submitted an application to the GTR seeking approval to cultivate banana line QCAV-4 for commercial release in Australia. The GTR will make a decision in accordance with their relevant legislation in a separate regulatory process.

Food businesses intending to export / import fresh GM banana to / into New Zealand will need to consult with the New Zealand EPA about whether the fresh banana fruit would be considered a new organism and seek advice from the New Zealand MPI in relation to biosecurity requirements. Cultivation of banana line QCAV-4 in New Zealand would require an independent assessment and approval from EPA.

Further 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 banana line QCAV-4. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from banana line QCAV-4 is considered to be as safe for human consumption as food derived from non-GM banana cultivars.

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 banana line QCAV-4 in accordance with the Code to enable informed consumer choice (see Section 2.2.2 of this report).

2.4.2.3 *The prevention of misleading or deceptive conduct*

The provision of DNA sequence information by the applicant (as described in Section 2.2.3 of this report) addresses 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 by FSANZ for banana line QCAV-4 used the best scientific evidence available. 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 by FSANZ 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. Banana line QCAV-4 is a new food crop developed to provide banana growers an additional tool for maintaining crop yield under severe TR4 pressure.

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

Issues related to consumer information and safety are considered in Sections 2.2 and 2.3 of this report 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) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. 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 A1274 – Food derived from disease-resistant banana line QCAV-4) 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]

Christel Leemhuis
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 A1274 – Food derived from disease-resistant banana line QCAV-4) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Standard 1.2.1—Requirements to have labels or otherwise provide information

[1] Subsection 1.2.1—9(3)

Insert:

- (ba) for a food referred to in paragraph 1.2.1—6(1)(c)—information relating to foods produced using gene technology (see section 1.5.2—4);

Schedule 26—Food produced using gene technology

[2] Subsection S26—3(4) (at the end of the table)

Add:

- 11 Banana** (a) disease-resistant banana line QCAV-4

Attachment B – Draft Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1274 – Food derived from disease-resistant banana line QCAV-4) Variation

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 A1274 which seeks to amend the Code to permit the sale and use of food derived from a new food produced using gene technology (GM food) - banana line QCAV-4. Banana line QCAV-4 has been genetically modified for resistance to the fungal disease *Fusarium wilt tropical race 4 (TR4)*, also known as Panama disease. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation – the *Food Standards (Application A1274 – Food derived from disease-resistant banana line QCAV-4) Variation*.

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or

instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared the draft variation to amend Schedule 26 and Standard 1.2.1 of the Code for the following purposes:

- to permit the sale and use of food derived from a new GM food – banana line QCAV-4, in accordance with the Code (banana line QCAV-4 has been genetically modified for resistance to the fungal disease *Fusarium wilt tropical race 4 (TR4)*, also known as Panama disease); and
- to require that information about GM food be provided in accordance with sections 1.5.2—4 and 1.2.1—9 where whole or cut fresh fruit and vegetables (other than seed sprouts or similar products), e.g. fresh whole and cut bananas from this banana line, are sold in a package that does not obscure the nature or quality of the food.

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1274 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. The consultation period, including a call for submissions on the assessment and the draft variation, will run for six-weeks.

A Regulatory Impact Statement was not prepared for this application and variation. This reflects earlier advice by the Office of Impact Analysis (OIA) that a Regulatory Impact Statement is not required for applications relating to GM food. This is because applications related to permitting the use of GM foods that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the application is approved.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Clause 1 of the draft variation provides that the name of the variation is the *Food Standards (Application A1274 – Food derived from disease-resistant banana line QCAV-4) Variation*.

Clause 2 of the draft variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the draft variation provides that the variation will commence on the date of gazettal of the instrument.

Item [1]

Item [1] of the Schedule to the draft variation would amend Standard 1.2.1 of the Code by

inserting, in alphabetical order, the following new paragraph (ba) into subsection 1.2.1—9(3):

“(ba) for a food referred to in paragraph 1.2.1—6(1)(c)—information relating to foods produced using gene technology (see section 1.5.2—4);”

If the draft variation is approved, the effect of this amendment would be to require that information about GM food be provided in accordance with sections 1.5.2—4 and 1.2.1—9 where whole or cut fresh fruit and vegetables (other than seed sprouts or similar products), e.g. fresh whole and cut bananas from this banana line, are sold in a package that does not obscure the nature or quality of the food .

This amendment is consequential to the amendment in item [2] of the draft variation (see below). **[Item 2]**

Item [2] of the Schedule to the draft variation would amend Schedule 26 of the Code by adding new item 11 at the end of the table to subsection S26—3(4).

The table to subsection S26—3(4) lists permitted GM food of plant origin.

New item 11 would consist of the following entries:

- column 1 (**‘Commodity’**) – references to ‘11’ as the new item number and ‘Banana’ as the new commodity; and
- column 2 (**‘Food derived from’**) – a reference to ‘(a) disease-resistant banana line QCAV-4’ as a permitted GM food.

If the draft variation is approved, the effect of this amendment would be to permit the sale and use of food derived from banana line QCAV-4 in accordance with the Code.