

**16 February 2024**  
**281-24**

Approval report – 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.

On 25 September 2023, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received 68 submissions.

FSANZ approved the draft variation on 2 February 2024. The Food Ministers' Meeting<sup>1</sup> was notified of FSANZ's decision on 16 February 2024.

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

---

<sup>1</sup> Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

# Table of contents

<b>EXECUTIVE SUMMARY .....</b>	<b>3</b>
<b>1 INTRODUCTION .....</b>	<b>4</b>
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
1.6 DECISION .....	5
<b>2 SUMMARY OF THE FINDINGS .....</b>	<b>6</b>
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS .....	6
2.2 SAFETY ASSESSMENT .....	18
2.3 RISK MANAGEMENT .....	18
2.3.1 <i>Regulatory approval</i> .....	18
2.3.2 <i>Labelling</i> .....	19
2.3.3 <i>Detection methodology</i> .....	19
2.4 RISK COMMUNICATION .....	20
2.4.1 <i>Consultation</i> .....	20
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS .....	20
2.5.1 <i>Section 29</i> .....	20
2.5.2 <i>Subsection 18(1)</i> .....	23
<b>3 DRAFT VARIATION .....</b>	<b>24</b>
<b>4 REFERENCES .....</b>	<b>24</b>
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE .....	27
ATTACHMENT B – EXPLANATORY STATEMENT .....	29

## Supporting document

The [following document](#)<sup>2</sup> which informed the assessment of this application are available on the FSANZ website:

SD1          Supporting Document 1 – Safety assessment report

---

<sup>2</sup> <https://www.foodstandards.gov.au/food-standards-code/applications/A1274-Food-derived-from-disease-resistant-banana-line-QCAV-4>

# 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.

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, is the protection of public health and safety. Accordingly, the 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).

The applicant has stated that Australia's banana industry mainly serves the domestic market. New Zealand imports a small amount of fresh banana from Australia. Cultivation of banana line QCAV-4 in New Zealand would require an independent assessment and approval from New Zealand Environmental Protection Authority (EPA).

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

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 25 September 2023. 68 submissions were received in the six-week consultation period. FSANZ has had regard to all submissions (see section 2.1).

For reasons summarised in this report, FSANZ has decided to approve the draft variation proposed at the call for submissions without change.

The effects of the approved draft variation will 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.

# 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 11 previous applications<sup>3</sup>.

The applicant is seeking a licence for the commercial cultivation of banana line QCAV-4 in Australia from the Gene Technology Regulator (GTR)<sup>4</sup>. This requires a separate regulatory assessment which is being undertaken by the Office of the GTR (OGTR).

The applicant has stated that Australia's banana industry mainly serves the domestic market. New Zealand imports a small amount of fresh banana from Australia<sup>5, 6</sup>. 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 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

---

<sup>3</sup> A341, A355, A372, A379, A382, A383, A384, A484, A549, A595, A1029

<sup>4</sup> 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*

<sup>5</sup> Reference provided by New Zealand Food and Grocery Council: [New Zealand | Imports and Exports | World | Bananas | Value \(US\\$\) and Value Growth, YoY \(%\) | 2011 - 2022 \(trendeconomy.com\)](#)

<sup>6</sup> The New Zealand Environmental Protection Authority (EPA) has advised that food businesses intending to export / import fresh GM banana to / into New Zealand will need to consult the EPA about whether the fresh banana fruit would be considered a new organism. Additionally, the New Zealand Ministry for Primary Industries (MPI) has advised that food businesses should seek advice about biosecurity requirements from MPI.

'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*<sup>7</sup>. 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 also 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 was assessed under the General Procedure.

## 1.6 Decision

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

---

<sup>7</sup> 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*).

## 2 Summary of the findings

### 2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation to the Code on 25 September 2023. The consultation period was six weeks.

A total of 68 submissions were received, of which 65 were opposed to the draft variation. Of these submissions, 43 were related to a campaign initiated by GE Free New Zealand. The campaign included submissions by:

- 36 private individuals
- 7 non-government organisations (NGOs):
  - GE Free NZ
  - Auckland GE Free Coalition
  - GE Free Tai Tokerau
  - Physicians and Scientists for Global Responsibility (PSGR)
  - Pacific Organic and Ethical Trade Community (POETC)
  - A joint submission by Transition Towns BOI-WH Flora and Fauna of Aotearoa, and Far North Resilient Communities Charitable Trust
- 1 Industry
  - Manuka Farm Ltd

Some individuals/organisations who participated in the joint campaign submission also provided a second submission.

Further submissions opposing the draft variation were also received from 19 private individuals, Gene Ethics, Spring Creek Organics, and Frog Safe Inc.

The submitters that supported the proposed draft variation were:

- New South Wales Food Authority (NSWFA)
- New Zealand Food Safety (NZFS)
- New Zealand Food and Grocery Council (NZFGC).

NSWFA, NZFS and NZFGC stated their agreement with FSANZ's safety assessment conclusions (section 2.2) that no potential public health and safety concerns have been identified and that food from banana line QCAV-4 is safe for human consumption. The NZFGC further noted that banana line QCAV-4 will be a good alternative for countries whose banana plantations are severely affected by Panama disease, as well as having the potential to increase food security and sustainability.

Many of the submissions received by FSANZ raised issues that are outside the scope of FSANZ's regulatory remit. The issues raised included issues related to the environment, commerce and trade, crop development and agricultural practices, and general GM issues not directly related to FSANZ's food safety assessment. The regulation of gene technology in Australia is undertaken by the [GTR](#) and the [EPA](#) in New Zealand. FSANZ directs submitters who would like more information about the environmental impact of GM banana to see OGTR's [safety assessment](#).

Responses to issues raised in submissions are provided in Table 1.

**Table 1: Summary of issues raised or implied by submissions**

No	Issue	Raised by	FSANZ response
<b>FSANZ process</b>			
1	Submitters stated that the information provided by FSANZ to date does not give the public confidence on the effective, transparent, and accountable regulatory framework assessment (FSANZ Act 1991, Section 3).	GE Free New Zealand AGEFC; GEFTT; Private individuals (Campaign); PSGR	<p>Noted.</p> <p>FSANZ does not agree.</p> <p>FSANZ has undertaken a comprehensive assessment of the application and has published the application dossier, the full safety assessment (SD1) and the reasons for its decision. A plain-English overview of the application is also available on the <a href="#">website</a><sup>8</sup>. In publishing this information, FSANZ has acted in accordance with relevant legislation and policy.</p> <p>FSANZ remains satisfied that it has assessed this application in an open, transparent, and accountable way and has reached a decision based on a risk analysis informed by the best available scientific evidence. On that basis, the public can be confident that the GM banana is safe to eat and that a rigorous and open regulatory process was followed.</p>
2	The public consultation period was insufficient. The call for submission was not publicised in the mainstream media.	Private individuals (D.C.; K.F.)	<p>Noted.</p> <p>FSANZ does not agree.</p> <p>FSANZ followed its standard public consultation process where the call for submissions was notified and publicised via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standards News. Subscribers and interested parties were also notified. Similar to other applications, the public comment period was 6 weeks.</p> <p>FSANZ notes that no requests were received for an extension to the timeframe for submissions.</p>
<b>Safety issues</b>			
3	<p>Submitters raised a number of issues relating to deficiencies in FSANZ's safety assessment process, noting:</p> <ul style="list-style-type: none"> <li>The data on which FSANZ relied</li> </ul>	GE Free NZ; PSGR; Private individuals (Campaign); Joint	<p>Noted.</p> <p>FSANZ does not agree for the following reasons.</p> <p>The applicant provided a complete data package in accordance with FSANZ data requirements</p>

<sup>8</sup> <https://www.foodstandards.gov.au/food-standards-code/applications/A1274-Food-derived-from-disease-resistant-banana-line-QCAV-4>

	<p>on in its assessment was insufficient. Submitters suggested that skin prick analysis should have been conducted.</p> <ul style="list-style-type: none"> <li>Absence of long-term feeding/consumption studies of the GM banana in humans and animals.</li> <li>There is no study of different impact for infants, children, the sick or elderly from eating the GM bananas.</li> <li>Robust scientific testing needs to be conducted.</li> </ul>	<p>submission; AGEFC; GEFTT; Spring Creek Organics</p>	<p>(Guidelines 3.1.1 and 3.5.1 of the <a href="#">Application handbook</a><sup>9</sup>).</p> <p>FSANZ has conducted a comprehensive safety assessment which considered the data submitted by the Applicant, plus other information from the scientific literature. FSANZ's assessment approach is consistent with the Codex Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants.</p> <p>Skin prick studies are neither necessary nor appropriate for the assessment of the potential allergenicity of banana line QCAV-4. Such studies are suggested by the Codex Guideline as a possible additional test that can be done where a new protein is derived from a known allergenic source, and if other studies, such as specific serum screening, are equivocal in their findings. The new protein expressed in banana line QCAV-4 however is not from a known allergenic source, therefore the standard approach, using bioinformatic and digestibility studies, is adequate to determine potential allergenicity. FSANZ's assessment concluded the new protein is not allergenic to humans.</p> <p>Animal feeding studies and human clinical studies generally do not add value to the safety assessment and are not justified on a routine basis. Such studies would only be requested by FSANZ if any new or altered hazard as a result of genetic modification were identified in the safety assessment and could only be addressed by such studies.</p> <p>In the case of banana line QCAV-4 no such issues were identified. In the absence of any new or altered hazards, a study in vulnerable populations is not warranted, ethical or in line with internationally established scientific principles and guidelines. More information about the role of animal feeding studies can be found on the <a href="#">FSANZ website</a><sup>10</sup>.</p> <p>The safety assessment concluded that banana line QCAV-4 is as safe and nutritious as conventional non-GM bananas already in the Australian and New Zealand food supply.</p>
4	<p>Submitters raised a range of issues regarding the antibiotic-resistance gene (<i>nptII</i>). These include:</p> <p>(a) horizontal gene transfer (HGT) to pathogens (Wellington et al. 2013) or gut bacteria leading to resistance to kanamycin-type antibiotics;</p> <p>(b) lack of experimental data</p>	<p>GE Free New Zealand; AGEFC; GEFTT; Private Individuals (Campaign); Spring Creek Organics; Gene Ethics;</p>	<p>FSANZ notes these issues.</p> <p>The safety of the <i>nptII</i> gene and its encoded protein (NPTII) is well established. NPTII functions as a selectable marker during the initial laboratory stages of plant cell selection following plant transformation. GM crops expressing NPTII were first commercialised in the 1990s and NPTII has a long history of safe use in food, with safety data accumulated over 25 years (Avisar et al. 2023).</p> <p>In response to the submitters' specific issues:</p> <p>(a) HGT of antibiotic resistance genes from food products to gut microorganisms is regarded as a</p>

<sup>9</sup> [Application Handbook | Food Standards Australia New Zealand](#)

<sup>10</sup> <https://www.foodstandards.gov.au/consumer/gmfood/roleofanimalfeedings3717>



	<p>documenting the safety of using antibiotic-resistance gene in GM bananas;</p> <p>(c) use of bacterial antibiotic resistance gene for resistance against the fusarium fungus;</p> <p>(d) outdated references to cite the safety of the <i>nptII</i> gene. Ramirez and Tolmasky (2010) was not cited;</p> <p>(e) the failure of Calgene's Flavr Savr tomato was due to the use of NPTII. The FDA had raised safety concerns for the use of NPTII in Flavr Savr tomato 1992 and 1993;</p> <p>(f) suggestion that approval of GM bananas be contingent on the applicant removing all antibiotic resistance marker genes.</p>	<p>PSGR; Private individuals (E.D.; M.R.)</p>	<p>rare possibility because of the many complex and unlikely events that would need to occur consecutively. Additionally, humans are already exposed to the <i>nptII</i> gene due to its widespread environmental presence, including in bacteria found naturally in the digestive tract. Human health impacts are therefore considered to be negligible. Further information on HGT of antibiotic resistance genes can be found on FSANZ's <a href="#">Safety assessment of GM foods webpage</a><sup>11</sup>.</p> <p>(b) In assessing the banana, FSANZ considered the safety of the <i>nptII</i> gene and the encoded NPTII protein, and no safety concerns were identified.</p> <p>(c) NPTII does not provide resistance against the fusarium fungus. Disease-resistance to the fusarium fungus is conferred by the <i>MamRGA2</i> gene. For more details, please see section 3 of the SD1.</p> <p>(d) The safety of the <i>nptII</i> gene is supported by over 25 years of accumulated history of safe use in GM crops (FDA 1998; EFSA 2004; EFSA 2009; OGTR 2017). A more recent paper adds further support to the safety of the <i>nptII</i> gene (Avisar et al. 2023). The Ramirez and Tolmasky (2010) review confirms the ubiquitous presence of microorganisms carrying genes encoding aminoglycoside modifying enzymes and does not raise any specific safety issue related to the <i>nptII</i> gene.</p> <p>(e) FSANZ refers submitters to an article by Bruening and Lyons (2000) and Lobato-Gómez et al. (2021), which examine the reasons for the decline in sales of Calgene's Flavr Savr tomato. This does not include the United States FDA having safety concerns for the use of NPTII. In fact, the United States FDA declared that using NPTII as a selectable marker in GM plants does not pose a risk to human or animal health or the environment (FDA 1998).</p> <p>(f) For the reasons set out in this report and SD1, FSANZ remains satisfied that the <i>nptII</i> gene or the NPTII protein does not pose a public health and safety concern. Rejecting Application A1274 on the basis of the use of this antibiotic resistance marker gene would not be scientifically justified.</p>
<p>5</p>	<p>Submitters expressed concerns about:</p> <ul style="list-style-type: none"> <li>the survival / persistence of the transgene in the gut, noting that bananas are eaten fresh (Schubbert et al. 1997; Ewen and Pusztai 1999; Nawaz et al. 2019);</li> </ul>	<p>GE Free NZ; AGEFC; GEFTT; Private individuals (Campaign)</p>	<p>FSANZ notes these concerns.</p> <p>There are no safety concerns regarding the presence of 'transgenes' in food, whether that food is eaten fresh or cooked. DNA is a natural part of the human diet, as it is present in the cells of plants and animals. The human body does not distinguish between transgenes, and other DNA that is naturally present in a wide variety of foods. Both types of DNA are chemically indistinguishable and are thoroughly broken down during digestion.</p>

<sup>11</sup> <https://www.foodstandards.gov.au/consumer/gmfood/safety>

	<ul style="list-style-type: none"> <li>a lack of evidence on the impact of different medicines that change the survival rate of GM constructs into the gut and bloodstream of consumers.</li> <li>the effects of the transgenes and inflammatory response in small bowel flora, villi and epithelium, in long-term studies.</li> </ul>		<p>There is no scientifically plausible basis to expect that transgenes would have different impacts in the human gut, small bowel flora, villi and epithelium compared to other DNA in the diet, or that human drugs or medicines would preferentially change the survival of transgenes in the gut and bloodstream, compared to other DNA ingested in the diet.</p> <p>This issue has been considered in detail by FSANZ and a summary is available on the <a href="#">FSANZ website</a><sup>12</sup>.</p> <p>The three studies cited have been previously considered by in detail by <a href="#">FSANZ</a><sup>13</sup>.</p>
6	FSANZ must require laboratory diagnostic tests for detection of the transgenes be made available for health professionals before any approval of the product.	GE Free New Zealand; AGEFC; GEFTT; Private individuals (Campaign)	<p>FSANZ does not agree.</p> <p>It is not FSANZ's role to develop a detection methodology for transgenes. FSANZ's safety assessment did not identify any risk or hazard associated with the transgenes, therefore, development of a detection methodology is not warranted.</p>
7	Banana is a recognised allergenic food with several major allergens identified. It would be beneficial to comment on whether any studies have identified the R-protein (MamRGA2) among the known banana allergens.	NZFS	<p>Noted.</p> <p>FSANZ's safety assessment did not identify MamRGA2 as a known banana allergen, nor does it have any similarity to known allergenic proteins. The safety of MamRGA2 is addressed in section 4.1 of SD1.</p> <p>FSANZ notes that homologs of the R-protein have been identified in the Cavendish banana and are often found in many other food crops with a history of safe use, including tomato, rice, soybean, maize, potato, chickpea, bean, cassava, sorghum, and wheat.</p>
8	<p>FSANZ did not examine the safety of new proteins in the banana:</p> <p>(a) No evidence on whether people with gut dysfunction put them at risk of only partially digesting antimicrobial</p>	GE Free NZ; Gene ethics	<p>FSANZ does not agree for the following reasons.</p> <p>FSANZ's assessment of the MamRGA2 and NPTII proteins are found in section 4.1. and 4.2. of the SD1. In response to the submitters' specific issues:</p> <p>(a) FSANZ notes that a large and diverse range of proteins are ingested as part of the normal human diet without any adverse effects. The NPTII protein does not have any characteristics</p>

<sup>12</sup> <https://www.foodstandards.gov.au/consumer/gmfood/safety-of-ingested-recombinant-DNA>

<sup>13</sup> <https://www.foodstandards.gov.au/consumer/gmfood/adverse>

	<p>proteins.</p> <p>(b) The simulated gastric fluid (SGF) tests were not conducted on human gastric fluids but porcine gastric mucosa pepsin, which may have a different outcome to the secretion factors in human gastric fluids.</p>		<p>that would raise concerns if it was completely and/or partially digested in the gut. The bioinformatic analyses in section 4.2.3 of the SD1 confirms that NPTII does not have any similarities to known allergens and toxins.</p> <p>(b) The SGF assay conditions are well defined, validated and used internationally. Although the SGF tests are conducted on porcine gastric mucosa pepsin, the SGF assay was developed to mimic human gastric conditions and, as such, provides a standardised test to evaluate the digestibility of a protein (Thomas et al. 2004).</p>
9	<p>There is no analysis of seven new and unintended proteins identified in the GM banana.</p> <p>There is no research on the implications of these proteins for food safety when the banana is eaten.</p>	<p>GE Free New Zealand; AGEFC; GEFTT; Private individuals (Campaign); PSGR; Manuka Farm Ltd; Private individual (E.D.)</p>	<p>FSANZ does not agree for the following reasons:</p> <p>There is no evidence to indicate any unintended expression of new proteins in the banana.</p> <p>The analysis being referred to is the open reading frame (ORF) analysis, which identified 7 novel ORFs created in QCAV-4 as a result of the genetic modification. For more details please see section 3.4.5 of the SD1.</p> <p>As part of the analysis, each of the corresponding 7 putative peptides was assessed for their potential allergenicity and toxicity. It is highly unlikely that any proteins or peptides would be expressed from these ORFs as they do not have the appropriate signals for expression. The ORF analyses are therefore highly theoretical but demonstrate that, should any of the proteins/peptides be expressed, they are unlikely to be toxic or allergenic to humans.</p>
10	<p>Submitters were concerned for the presence of unknown allergens or toxins resulting from the genetic modification. Specific issues include:</p> <p>(a) increase in allergenicity or toxicity, referring to a 1996 study on a Brazil nut gene in a GM soybean.</p> <p>(b) current weight-of-evidence approach is inadequate to predict allergenicity of GM whole foods, referring to an opinion paper from EFSA (2022).</p>	<p>GE Free NZ; PSGR; Private individuals (E.D.; M.R.)</p>	<p>FSANZ notes these concerns.</p> <p>The current weight of evidence approach for allergenicity risk assessment of whole GM foods is based on the principles and guidelines of the Codex Alimentarius for the safety assessment of <i>Foods derived from modern biotechnology</i>, which was initially published in 2003 (Codex 2009). Since 2003, the allergenicity assessment protocol proposed by Codex has been subjected to scientific scrutiny and has proven to be a robust approach for whole food allergenicity assessments. This assessment approach is widely adopted and implemented by regulators around the world, including FSANZ and the European Food Safety Authority (EFSA).</p> <p>The safety assessment of GM banana concluded there are no allergenic or toxicity concerns. FSANZ directs submitters to section 3.4.5 and 4 of the SD1. In response to the submitters' specific issues:</p> <p>(a) The reference is to a historic case where a Brazil nut allergen was unintentionally transferred to soybean. The GM soybean was developed in the 1990s but never progressed beyond the research stage once the allergen transfer was confirmed. Further information about this study</p>

			<p>can be found in the following paper: (Moreno and Clemente 2008).</p> <p>There is no credible scientific basis to support the notion that food allergies are linked to the commercialisation of any GM crops or that allergens can arise spontaneously as a result of the genetic modification process (Goodman and Tetteh 2011). Similarly, there is no evidence that toxins can arise spontaneously as a result of the genetic modification process (Bartholomaeus et al. 2013). For more details on unintended effects, please see FSANZ's response to issue number 12.</p> <p>(b) The EFSA opinion paper (EFSA 2022) states that the weight-of-evidence approach still remains valid for current GM foods. The paper acknowledges there are knowledge gaps for certain criteria for the assessment of more complex biotech foods in the future.</p>
11	New omics tools should be a required safety test.	GE Free NZ	<p>FSANZ does not agree for the following reasons.</p> <p>'Omics' is a generic term referring to non-targeted, profiling approaches that can measure a broad and large number of molecules (nucleic acids, proteins, metabolites) in the cell. While the value of 'omics' for research purposes is well-documented, their value for GM food safety assessment is less clear, especially since experimental conditions need to be properly controlled in order for the data to be meaningful. Several proteomic studies, for example, have repeatedly confirmed that the genetic engineering process does not lead to unintended changes in GM crops (Gong and Wang 2013). When differences were seen, these were associated with differences in agronomic practices, detection methodologies or disruption of endogenous genes. Further information can be found in the following papers: (Cellini et al. 2004; Chassy 2010; Ricoch 2013).</p>
12	Concerns regarding unintended effects of the genetic engineering.	PSGR; GE Free NZ; Private individuals (E.D.; M.R.)	<p>FSANZ notes these concerns.</p> <p>However, the occurrence of unintended effects is not a phenomenon that is specific to genetic engineering, but also occurs in conventional breeding. The accumulated evidence and regulatory experience over the last 25 years does not support the hypothesis that GM foods have a greater propensity for unintended effects or that the technology is itself inherently harmful or a major source of risk to the consumer, compared to conventional forms of breeding (Herman and Price 2013; Ricoch 2013; Ladics et al. 2015; Schnell et al. 2015; FSANZ 2019; FSANZ 2021).</p>
13	General safety concern of GM foods e.g. allergens, toxins and human immune system.	Private individuals; GE Free NZ; AGEFC;	<p>Noted.</p> <p>Many concerns regarding the safety of GM foods can be traced back to a handful of studies reporting adverse effects in animals. A <a href="#">response by FSANZ</a><sup>14</sup> to some of these studies is available on our</p>

<sup>14</sup> <https://www.foodstandards.gov.au/consumer/gmfood/adverse>

		GEFTT; Gene Ethics; PSGR; POETC; Joint submission; Manuka Farm Ltd; Frog Safe Inc; Spring Creek Organics.	<p>website. Further analyses of some of the other studies can be found in Snell et al. (2012); Ricroch (2013); Ricroch et al. (2014).</p> <p>FSANZ conducts a thorough safety assessment of all GM foods before they are allowed in the food supply. This assessment ensures that any approved GM foods are as safe and nutritious as comparable non-GM foods already in the Australian and New Zealand food supply. Further information can be found on the following <a href="#">FSANZ webpage</a><sup>15</sup>.</p>
14	Animals have higher mortality rates when fed with GM crops. A paper was provided ( <a href="https://pubmed.ncbi.nlm.nih.gov/31370250/">https://pubmed.ncbi.nlm.nih.gov/31370250/</a> )	Private individual (K.E.)	The study cited here relates specifically to herbicide-tolerant corn sprayed with the herbicide glyphosate and fed to the common fruit fly <i>Drosophila melanogaster</i> . The study is not relevant to the food safety assessment of disease-resistant GM banana.
<b>Compositional analysis</b>			
15	The inclusion of only a single field site in the development of test material for compositional comparisons is a limitation of the application.	NZFS	<p>Noted.</p> <p>While FSANZ does not prescribe the number of field trial sites, the Application handbook states: 'where the number of trial sites is limited, consideration should be given to repeating the trials over more than one season' (Section 2.3.5, page 47). Unlike many other crops, banana plants are not resown each season. However, multiple generations of banana line QCAV-4 were grown at the field trial site over 5 years (section 5.2 of SD1). This would be comparable with trials being conducted over more than one season.</p> <p>FSANZ notes that the management and control of TR4 would have been a limiting factor in the selection of appropriate field sites. The only location banana plants can be assessed against TR4 is in the Northern Territory where the disease has become endemic. Although TR4 has been reported in five farms in the major banana-producing area of North Queensland, strict biosecurity restrictions preclude the trialling of the GM banana plants at these locations.</p>
16	For the compositional analysis of the GM banana line QCAV-4 and the control Grand Nain, there was a relatively narrow range of components (10) being analysed compared to other GM food assessments.	NZFS	<p>Noted.</p> <p>The primary banana food product consumed by humans is the flesh of the fruit. Because there is no OECD Consensus Document on compositional considerations for banana, key components were selected based on the highest contributors to the percent daily values from a 2,000 calorie reference diet for adults and children aged four and up. The key components analysed for the comparison of GM</p>

<sup>15</sup> <https://www.foodstandards.gov.au/consumer/gmfood/gmoverview>

			<p>and conventional banana include: proximates, vitamins and minerals.</p> <p>The compositional analysis did not include fatty acids, amino acids, anti-nutrients or dietary fibre as these are not considered key components for banana. For more details please see section 5.1 of the SD.</p>
17	<p>Given the relatively high sugar content of bananas (~15%), the comparison of the sugar contents and composition of QCAV-4 and the Grand Nain may be a useful additional check that no unintended compositional changes have resulted from the genetic modification.</p>	NZFS	<p>FSANZ does not agree.</p> <p>FSANZ does not expect to see any biologically relevant differences in the sugar content between banana line QCAV-4 and the conventional non-GM banana. Reasons include:</p> <ul style="list-style-type: none"> <li>the carbohydrate content, calculated as carbohydrate by difference<sup>16</sup>, is inclusive of sugar content. The mean values for carbohydrate in both the flesh and peel of QCAV-4 fruit were within the control and/or the publicly available range. See section 5.3 of the SD1;</li> <li>the purpose of the genetic modification did not include altering the nutritional characteristics, including carbohydrate composition, of QCAV-4.</li> </ul>
18	<p>There were statistically significant differences in mean values between the flesh of banana line QCAV-4 and the control.</p> <p>GM banana is different to the conventional counterpart.</p>	Spring Creek Organics; GE free NZ	<p>FSANZ does not agree the composition of the GM banana is different to the conventional counterpart.</p> <p>While some statistically significant compositional differences exist between banana line QCAV-4 and the conventional control, these are small in magnitude and not biologically relevant, as the differences are within the range of natural variation that exists for bananas. FSANZ concluded that food derived from banana line QCAV-4 is compositionally equivalent to food derived from conventional non-GM banana.</p> <p>For more details please see section 5 of the SD1.</p>
19	<p>Dietary exposure assessment should be undertaken based on culturally diverse patterns of consumption.</p>	Gene Ethics	<p>FSANZ does not agree for the following reasons.</p> <p>As specified in the FSANZ Application handbook, a dietary exposure assessment would only be considered if the GM food has altered nutritional characteristics. Assessing the nutritional adequacy of a GM food can, in most cases, be achieved through an understanding of the genetic modification and its consequences, together with a compositional analysis. FSANZ did not identify any altered nutritional characteristics in the GM banana, therefore a dietary exposure assessment based on any consumption patterns is unwarranted. For more details, please see section 6 of the SD1.</p>

<sup>16</sup> In this method, the moisture, protein, fat, ash, and alcohol content of a food are determined and then subtracted from the total weight of the food, and the remainder (or difference) is total carbohydrate.

Labelling			
20	Bananas are fresh products. Strict labelling requirements should be enforced, monitored and complied with appropriately so that a purchaser is clearly informed.	Spring Creek Organics; Gene Ethics; GEFTT	<p>Existing labelling requirements that would apply to food derived from banana line QCAV-4 are set out in section 2.3.2 of this report. FSANZ is of the view that those requirements, with which the relevant food businesses must comply, will enable informed consumer choice.</p> <p>The responsibility for monitoring compliance and enforcing Code requirements lies with state and territory enforcement agencies in Australia, and with the Ministry for Primary Industries in New Zealand.</p> <p>Australian and New Zealand regulators established the <a href="#">National Compliance and Monitoring Strategy of GM Foods<sup>17</sup></a> in 2010 for the purpose of enabling consistent and effective monitoring and surveillance of GM foods for sale.</p>
Other issues			
21	The applicant stated that Australia's banana industry mainly serves the domestic market, therefore fresh fruit derived from the GM banana was unlikely to be exported and sold in Zealand if approved to be cultivated in Australia. However, New Zealand does import fresh bananas from Australia but at a very low level.	NZFGC	<p>Noted.</p> <p>FSANZ has incorporated this information in section 1.2 of this report.</p>
22	<p>Submitters raised several issues relating to FSANZ's consideration of cost and benefits, including analysis:</p> <ul style="list-style-type: none"> <li>for ill health as a consequence of eating the GM banana.</li> <li>financial risk to farmers</li> </ul>	GE Free NZ; Private Individual (E.R.)	<p>FSANZ's notes these submissions and responds as follows.</p> <p>FSANZ has concluded that food derived from banana line QCAV-4 is equivalent to food from conventional non-GM banana in terms of its safety, therefore costing for ill health is therefore not necessary. In terms of costs vs benefits to farmers, this issue has been addressed in section 2.5.1.1. of this report, where due to the voluntary nature of this permission, banana growers (farmers) will only grow this banana line where they believe a net commercial benefit exists.</p>

<sup>17</sup> <https://www.foodregulation.gov.au/resources/publications/national-compliance-and-monitoring-strategy-genetically-modified-foods>

23	Has the GM banana been tested by human tasters for palatability?	Private individual (E.D.)	<p>FSANZ's assessment did not consider palatability of the food because palatability is not relevant to an assessment of public health and safety under the FSANZ Act and, nor does palatability come within any of the matters that FSANZ must consider under section 18 of that Act. Consequently, FSANZ is not required to consider palatability in developing or reviewing variations of food regulatory measures.</p> <p>Nevertheless, FSANZ does not expect any changes in the palatability of GM banana fruit. The purpose of the genetic modification did not include altering the taste or composition of the banana fruit. This is supported by the results of compositional analysis found in Section 5 of the SD1.</p>
24	Australia has a worldwide reputation of not growing genetically modified food and this introduction would harm Australia's overseas reputation.	Spring Creek Organics	<p>FSANZ does not agree for the following reasons.</p> <p>GM crops are already grown in Australia. The GTR grants approvals for field trials and commercial cultivation of GM crops in Australia. Please visit the <a href="#">OGTR webpage</a><sup>18</sup> for the complete list of GM crops currently grown in Australia.</p>
25	The CFS did not state if the plants would be grown in Australia or, as banana fruit contains seed, whether there is a biosecurity risk.	Spring Creek Organics	<p>FSANZ's CFS document states that banana line QCAV-4 may be grown in Australia subject to approval and licencing for commercial cultivation from the GTR. Please see the <a href="#">OGTR website</a><sup>19</sup> for more details on the commercial cultivation approval for banana line QCAV-4.</p> <p>Biosecurity risk is outside of FSANZ's regulatory remit. The authorities primarily responsible for managing biosecurity risk are <a href="#">the Department of Agriculture, Fisheries and Forestry</a><sup>20</sup> in Australia and <a href="#">MPI</a><sup>21</sup> in New Zealand.</p> <p>However, please note that commercially cultivated bananas do not contain seeds.</p>
26	Diseases can be traced back to a lack of nutrients. Healthy plants can prevent diseases.	Spring Creek Organics	<p>Noted.</p> <p>The compositional analyses have demonstrated that the genetic modifications have not altered the nutrient composition of banana line QCAV-4. For more details, please see section 6 of the SD1.</p> <p>FSANZ refers the submitter to the following <a href="#">fact sheet</a> from Plant Health Australia on Panama disease to learn more about the disease, how it spreads and current measures taken to control this disease.</p>

<sup>18</sup> [https://www.ogtr.gov.au/resources/publications/genetically-modified-gm-crops-australia#:~:text=Four%20genetically%20modified%20\(GM\)%20crops,growing%20or%20importing%20into%20Australia](https://www.ogtr.gov.au/resources/publications/genetically-modified-gm-crops-australia#:~:text=Four%20genetically%20modified%20(GM)%20crops,growing%20or%20importing%20into%20Australia)

<sup>19</sup> <https://www.ogtr.gov.au/gmo-dealings/dealings-involving-intentional-release/dir-199>

<sup>20</sup> <https://www.agriculture.gov.au/biosecurity-trade/policy/australia>

<sup>21</sup> <https://www.mpi.govt.nz/>



27	The GM banana will threaten the unique position of New Zealand being GMO free	Private individual (D.P.)	<p>FSANZ notes this concern.</p> <p>However, FSANZ's approval of the sale and use of food derived from banana line QCAV-4 would not allow GM banana plants to be brought in to New Zealand and cultivated. As stated above at section 1.2, cultivation of banana line QCAV-4 in New Zealand would require an independent assessment and approval from the EPA in New Zealand.</p>
28	No long-term and inter-generational studies have been carried out on any GM crops.	Private individual (E.R.)	<p>FSANZ notes this concern.</p> <p>GM food has been in our food supply for over 25 years. During this time, safety assessments by FSANZ and other international regulators, as well as research from around the world, has shown that approved GM foods are as safe to eat as non-GM foods.</p> <p>FSANZ's assessment has concluded that food derived from banana line QCAV-4 is equivalent to food from conventional non-GM banana in terms of its safety, including in the long-term. Additional studies would not add any useful information.</p>

## 2.2 Safety assessment

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

## 2.3 Risk management

The risk management options available to FSANZ after consideration of submissions were to approve, amend or reject the draft variation to the Code that was the subject of the call for submissions.

For the reasons listed in this report, FSANZ decided to approve the draft variation without amendment (see Attachment A).

### 2.3.1 Regulatory approval

Banana line QCAV-4 is a GM food for Code purposes as it is developed from 'an organism which has been modified by gene technology'<sup>22</sup>. The approved draft variation will list banana line QCAV-4 in the table to subsection S26—3(4) (see item [2] of the draft variation in Attachment A). Following gazettal, this will provide permission for the sale and use of food derived from banana line QCAV-4 as a GM food in accordance with the Code.

The applicant is seeking a licence for the commercial cultivation of banana line QCAV-4 from the GTR. This requires a separate regulatory assessment which has been undertaken by the OGTR. If approved by the GTR, banana line QCAV-4 may be cultivated in Australia and food

---

<sup>22</sup> **Food produced using gene technology** is defined in subsection 1.1.2—2(3) of the Code as 'a food which has been derived or developed from an organism which has been modified by gene technology'.

derived from banana line QCAV-4 may be sold in Australia primarily as fresh fruit or as processed products. Cultivation of banana line QCAV-4 in New Zealand would require an independent assessment and approval from EPA.

### **2.3.2 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, 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 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, will contain novel DNA or novel protein and will 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 from banana line QCAV-4 will 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 noted 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.

The approved variation will amend subsection 1.2.1—9(3) so that information about GM food (including information about whole or cut fresh bananas from banana line QCAV-4) will 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 variation in Attachment A).

### **2.3.3 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-Committee<sup>23</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<sup>24</sup> based detection method. This sequence information was supplied by the applicant for A1274.

## **2.4 Risk communication**

### **2.4.1 Consultation**

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

The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions were invited on a draft variation which was released for public comment between 25 September 2023 and 8 November 2023. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standards News. Subscribers and interested parties were also notified about the availability of reports for public comment.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on applications to amend the Code. All submissions are considered as part of the decision making process by FSANZ. All comments are valued and contribute to the rigour of our assessment.

Documents relating to Application A1274, including submissions received, are available on the [FSANZ website](#)<sup>25</sup>.

The draft variation was considered for approval by the FSANZ Board having regard to all the submissions made during the call for submissions period.

## **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**

##### *Changes to Office of Impact Analysis requirements*

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)<sup>26</sup>. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for applications relating to GM foods. This is because applications relating to permitting the use of GM foods that have been determined to be safe are considered to be

---

<sup>23</sup> Now known as the Implementation Subcommittee for Food Regulation.

<sup>24</sup> Polymerase Chain Reaction.

<sup>25</sup> <https://www.foodstandards.gov.au/food-standards-code/applications/A1274-Food-derived-from-disease-resistant-banana-line-QCAV-4>

<sup>26</sup> [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](#)

minor and deregulatory in nature, as the use of the GM food will be voluntary if the draft variation related to the application is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

#### *Meeting FSANZ Act requirements*

FSANZ, however, gave consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act requirements. 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 banana line QCAV-4.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. The consideration of the costs and benefits in this section was 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 sought to highlight the likely positives and negatives of moving away from the status quo by permitting the sale and use of food derived from banana line QCAV-4.

#### *Costs and benefits of permitting the sale and use of food derived from banana line QCAV-4*

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 majority of the costs and benefits are likely to be experienced in Australia due to the TR4 outbreak.

#### **Impacts in Australia**

The Australian food industry may benefit from this application being approved.

The existence of TR4 disease in Australia is a significant risk for banana growers, and other parts of the industry that purchase Australian grown bananas including manufacturers and retailers.

This risk will be reduced if the application is approved, subject to other necessary legal processes and approvals. This includes approval from the OGTR to grow the bananas in Australia. The applicant has separately submitted an application with the OGTR for approval to grow the bananas. If the OGTR application is not approved the benefits will not be realised. Once approval is granted, growers will also need to obtain a licence from the applicant to grow the banana.

Separate approvals will be required to export the products from Australia to New Zealand, or to grow the bananas in New Zealand<sup>27</sup>. Australian growers do not export a significant quantity of bananas to New Zealand, therefore these approvals do not have a significant bearing on the net economic benefit of this proposal.

There is no cost to industry. Using the permission is voluntary and therefore anyone within the industry (including growers, manufacturers and retailers) will use the permission to sell the any product containing banana line QCAV-4 where a commercial net benefit exists for

---

<sup>27</sup> Other approvals required in New Zealand are discussed in section 1.2 of this Approval Report.

them.

Consumers will benefit if the risk of TR4 becoming widespread materialises.

All bananas consumed in Australia are grown in Australia. Data indicates Australians eat 5,000,000 bananas every day, and that 95 per cent of Australian households bought bananas in the financial year ending June 2021<sup>28</sup>.

Therefore, Australian consumers may have increased choice and a more reliable supply of foods derived from bananas in general, given banana line QCAV-4 is being marketed as being resistant to TR4.

There are not expected to be any significant costs to Australian consumers.

Consumers will have a choice on whether to consume the bananas. Genetically modified food is required to be labelled (as discussed in section 2.3.2 of this report) which provides information to consumers assist them in making an informed choice.

FSANZ has assessed that the GM banana line is safe to consume, therefore there will be no negative health impacts.

There are not expected to be any significant costs or impacts for governments. There may be small and likely inconsequential costs of monitoring an extra GM food ingredient for regulators to ensure compliance with labelling requirements.

### **Impacts in New Zealand**

In New Zealand there is not expected to be a significant impact on consumers, industry or the government.

The impacts on New Zealand is limited because:

- The TR4 outbreak is isolated to Australia, which limits the scope of the benefits
  - No grower in New Zealand will benefit
  - The benefits to industry in New Zealand is limited to any business that imports and uses or sells Australian bananas
- New Zealand only imports small amounts of bananas from Australia, greatly limiting the scale of the impact
- It is less certain whether the bananas will be able to be imported or grown in New Zealand
  - There less commercial benefit to seek other necessary approvals that would enable use or sale in New Zealand, due to TR4's minor impact in New Zealand.

#### *Conclusions from cost benefit considerations*

FSANZ's assessment at the call for submissions stage was that the direct and indirect benefits that would arise from permitting the sale and use of food derived from banana line QCAV-4, would most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

#### **2.5.1.2 Other measures**

There are no other measures (whether available to FSANZ or not) that would be more cost-

---

<sup>28</sup> [Australian Banana Growers – Our Industry](#)

effective than the food regulatory measures developed or varied as a result of the application.

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

As stated above, the applicant has stated that Australia's banana industry mainly serves the domestic market. New Zealand imports a small amount of fresh banana from Australia.

Therefore, the practical effects of the permission provided by the approved draft variation will be affected by the GTR's pending decision whether to approve the commercial cultivation of banana line QCAV-4 in Australia.

Cultivation of banana line QCAV-4 in New Zealand would require an independent assessment and approval from EPA.

Further relevant matters are considered below.

### **2.5.2. 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 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 conventional non-GM banana cultivars.

#### **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 banana line QCAV-4 in accordance with the Code to enable informed consumer choice (see section 2.3.2 of this report).

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

The provision of DNA sequence information by the applicant (as described in section 2.3.3) addresses this objective.

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

FSANZ has also had regard to:

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

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex 2009a). 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**

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 above.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

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**

Avisar D, Azulay S, Bombonato L, et al. (2023) Safety Assessment of the CP4 EPSPS and NPTII Proteins in Eucalyptus. *GM Crops Food*. 14(1):1-14.

Bartholomaeus A, Parrott W, Bondy G, Walker K, ILSI (2013) The use of whole food animal studies in the safety assessment of genetically modified crops: limitations and recommendations. *Crit Rev Toxicol*. 43 Suppl 2(Suppl 2):1-24.

Bruening G, Lyons JM (2000) The case of the FLAVR SAVR tomato. *California Agriculture*. 54(4):6-7.

Cellini F, Chesson A, Colquhoun I, et al. (2004) Unintended effects and their detection in genetically modified crops. *Food Chem Toxicol*. 42(7):1089-1125.



Chassy BM (2010) Can -omics inform a food safety assessment? . Regul Toxicol Pharmacol 58(S2-7)

Codex (2009) Food derived from modern biotechnology. Rome.

Codex (2009a) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. . Codex Alimentarius Commission. Rome.

EFSA (2004) Opinion of the Scientific Panel on Genetically Modified Organisms on the use of antibiotic resistance genes as marker genes in genetically modified plants. EFSA Journal. 2(4):48.

EFSA (2009) Consolidated presentation of the joint Scientific Opinion of the GMO and BIOHAZ Panels on the “Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants” and the Scientific Opinion of the GMO Panel on “Consequences of the Opinion on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants on Previous EFSA Assessments of Individual GM Plants”. EFSA Journal. 7(6):1108.

EFSA (2022) Scientific Opinion on development needs for the allergenicity and protein safety assessment of food and feed products derived from biotechnology. EFSA Journal. 20(1):e07044.

Ewen SW, Pusztai A (1999) Effect of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine. Lancet. 354(9187):1353-1354.

FDA U (1998) Guidance for industry: use of antibiotic resistance marker genes in transgenic plants. <https://www.federalregister.gov/documents/1998/09/08/98-24072/draft-guidance-for-industry-use-of-antibiotic-resistance-marker-genes-in-transgenic-plants-report>.

FSANZ (2019) Final report – Review of food derived using new breeding techniques. <https://www.foodstandards.gov.au/consumer/gmfood/Documents/NBT%20Final%20report.pdf>. Accessed July 2020.

FSANZ (2021) Safety assessment: full technical assessment: P1055 - Definitions for gene technology and new breeding techniques. FSANZ. Canberra, Australia.

Gong C, Wang T (2013) Proteomic evaluation of genetically modified crops: current status and challenges. Frontiers in Plant Science. 4

Goodman RE, Tetteh AO (2011) Suggested improvements for the allergenicity assessment of genetically modified plants used in foods. Curr Allergy Asthma Rep. 11(4):317-324.

Herman RA, Price WD (2013) Unintended Compositional Changes in Genetically Modified (GM) Crops: 20 Years of Research. Journal of Agricultural and Food Chemistry. 61(48):11695-11701.

Ladics GS, Bartholomaeus A, Bregitzer P, et al. (2015) Genetic basis and detection of unintended effects in genetically modified crop plants. Transgenic Res. 24(4):587-603.

Lobato-Gómez M, Hewitt S, Capell T, et al. (2021) Transgenic and genome-edited fruits: background, constraints, benefits, and commercial opportunities. Horticulture Research. 8

Moreno FJ, Clemente A (2008) 2S Albumin Storage Proteins: What Makes them Food Allergens? Open Biochem J. 2:16-28.

Nawaz MA, Mesnage R, Tsatsakis AM, et al. (2019) Addressing concerns over the fate of DNA derived from genetically modified food in the human body: A review. Food and

Chemical Toxicology. 124:423-430.

OGTR (2017) Risk Assessment Reference: Marker Genes in GM Plants: Office of the Gene Technology Regulator.

Ramirez MS, Tolmasky ME (2010) Aminoglycoside modifying enzymes. Drug Resist Updat. 13(6):151-171.

Ricroch A, Boisron A, Kuntz M (2014) Looking back at safety assessment of GM food/feed: An exhaustive review of 90-day animal feeding studies. Int. J. of Biotechnology 2014 Vol.13, No.4. 13:230-256.

Ricroch AE (2013) Assessment of GE food safety using '-omics' techniques and long-term animal feeding studies. N Biotechnol. 30(4):349-354.

Schnell J, Steele M, Bean J, et al. (2015) A comparative analysis of insertional effects in genetically engineered plants: considerations for pre-market assessments. Transgenic Res. 24(1):1-17.

Schubbert R, Renz D, Schmitz B, Doerfler W (1997) Foreign (M13) DNA ingested by mice reaches peripheral leukocytes, spleen, and liver via the intestinal wall mucosa and can be covalently linked to mouse DNA. Proc Natl Acad Sci U S A. 94(3):961-966.

Snell C, Bernheim A, Bergé JB, et al. (2012) Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: a literature review. Food Chem Toxicol. 50(3-4):1134-1148.

Thomas K, Aalbers M, Bannon GA, et al. (2004) A multi-laboratory evaluation of a common in vitro pepsin digestion assay protocol used in assessing the safety of novel proteins. Regul Toxicol Pharmacol. 39(2):87-98.

Wellington EM, Boxall AB, Cross P, et al. (2013) The role of the natural environment in the emergence of antibiotic resistance in gram-negative bacteria. Lancet Infect Dis. 13(2):155-165.

## **Attachments**

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

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



### Food Standards (Application 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 – 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 approved a draft variation – the *Food Standards (Application A1274 – Food derived from disease-resistant banana line QCAV-4) Variation*.

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

##### **2. Variation is a legislative instrument**

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation ([www.legislation.gov.au](http://www.legislation.gov.au)).

This instrument is not 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 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 approved 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 approved 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 25 September 2023 for a six-week consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)<sup>29</sup>. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement was not required for applications relating to GM foods. This is because applications relating to permitting the use of GM foods that have been determined to be safe are considered to be minor and deregulatory in nature, as the use of the GM food will be voluntary if the draft variation related to the application is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

### **6. 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 44 of the *Legislation Act 2003*.

### **7. Variation**

Clause 1 of the 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 variation provides that the Code is amended by the Schedule to the variation.

---

<sup>29</sup> [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](https://www.pmc.gov.au/regulatory-impact-analysis-guide-for-ministers-meetings-and-national-standard-setting-bodies)

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

**Item [1]**

Item [1] of the Schedule to the variation amends 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);”

The effect of this amendment will 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 variation (see below).

**[Item 2]**

Item [2] of the Schedule to the variation amends 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 consists 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.

The effect of this amendment is to permit the sale and use of food derived from banana line QCAV-4 in accordance with the Code.