30 July 2025
351-25

Call for submissions – Application A1333

Food derived from purple tomato lines containing event Del/Ros1-N

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Norfolk Healthy Produce Inc. to amend the Australia New Zealand Food Standards Code to permit the sale of genetically modified (GM) tomatoes containing event Del/Ros1-N for purple fruit colour. A draft food regulatory measure has been prepared. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application need to be made through the Consultation Hub.

All submissions on applications and proposals will be published on the Consultation Hub. 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 following consultation and before the next stage in the statutory assessment process.

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 Making a submission.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 10 September 2025

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.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission. 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:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6228 8226

Food Standards Australia New Zealand
PO Box 10559
WELLINGTON 6140
NEW ZEALAND
Tel +64 4 978 5630

Table of contents

Supporting document

The following document which informed the assessment of this application is available on the A1333 page on the FSANZ website[1]:

SD1 Safety assessment report

[1] https://www.foodstandards.gov.au/food-standards-code/applications/a1333-food-derived-purple-tomato-lines-containing-event-delros1-n

Executive summary

Food Standards Australia New Zealand (FSANZ) has received an application from Norfolk Healthy Produce, Inc. to vary the Australia New Zealand Food Standards Code (the Code) to permit food derived from genetically modified (GM) tomato lines containing event Del/Ros1-N (the GM Purple Tomato, or the purple tomato lines).

The GM Purple Tomato has been modified to produce natural blue pigments (anthocyanins) during ripening, resulting in both purple skin and flesh. If approved, the GM Purple Tomato fruit will be sold fresh or used as an ingredient in processed food products such as sun-dried tomatoes, pastes, purees and concentrates, ready-to-eat sauces, juices or tinned tomatoes.

The application relates only to the sale and use of the GM Purple Tomato as food. Cultivation, import or export will require approval from other Australian and New Zealand government agencies.

FSANZ has completed a safety assessment of the GM Purple Tomato based on the best available scientific evidence. The assessment found no public health or safety concerns. Food derived from the purple tomato lines is as safe for human consumption as food derived from conventional tomato varieties.

For the reasons summarised in this report, FSANZ has prepared a draft variation to amend Schedule 26 to insert a new item 12 in the table to subsection S26—3(4). The new item would contain a reference to ‘tomato lines containing event Del/Ros1-N’.

If approved, the effect of the draft variation would be to permit the sale of food derived from the purple tomato lines in accordance with the Code. Existing labelling requirements for GM food would apply.

FSANZ seeks submissions on the draft variation to Schedule 26 of the Code.

1 Introduction

1.1 The applicant

Norfolk Healthy Produce, Inc. is a company based in the United States that develops and commercialises tomato lines containing event Del/Ros1-N.

1.2 The application

Application A1333 was submitted to FSANZ on 16 May 2025. It seeks to amend the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from purple tomato lines containing event Del/Ros1-N. These lines have been genetically modified (GM) for purple fruit colour. The purple tomato lines express 3 novel substances, summarised in Table 1.

Table 1. Novel substances expressed in the purple tomato lines.

Protein	Gene	Gene donor organism	Function	Previously assessed by FSANZ?
Del	*Del (Delila)*	*Antirrhinum majus* (snapdragon)	Transcription factor (anthocyanin biosynthesis)	No
Ros1	*Ros1 (Rosea1)*	*A. majus*	Transcription factor (anthocyanin biosynthesis)	No
NPTII	*nptII*	*Escherichia coli*	Selectable marker (kanamycin resistance)	Yes (12 previous applications)

The applicant is also seeking approval from the Gene Technology Regulator (GTR) for commercial cultivation of the GM Purple Tomato in Australia. This requires a separate regulatory assessment which is being undertaken by the Office of the GTR (OGTR). [2]

Cultivation of the GM Purple Tomato in New Zealand would require approval from the Environmental Protection Authority (EPA)[3]. Food businesses in New Zealand intending to import fresh GM Purple Tomato would also need to consult the EPA and seek advice from the Ministry for Primary Industries (MPI)[4] in relation to biosecurity requirements.

1.2.1 Regulatory submissions to other countries

The applicant has submitted applications for regulatory approval of tomato lines containing event Del/Ros1-N to Canada and the US, as listed in Table 2.

[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/

Table 2. List of countries to whom applications for regulatory approval of Del/Ros1-N purple tomatoes have been submitted.

Country	Authority	Type of approval sought	Status
Canada	Health Canada (HC)	Food	Submitted
	Canadian Food Inspection Agency (CFIA)	Cultivation	Submitted
United States	United States Department of Agriculture (USDA)	Cultivation	Determined to not be a regulated article
	Food and Drug Administration (FDA)	Food	Letter of no questions issued

1.2.2 Safety assessment sharing with Health Canada

This is the sixth GM application assessed under the Health Canada-FSANZ Shared Assessment Process[5].

1.3 The current standard

Australian and New Zealand food laws require that food for sale must comply with the Code. The requirements in the Code relevant to this application are summarised below.

Pre-market approval

Standard 1.1.1 of the Code provides that, unless expressly permitted by the Code, a food for sale cannot be, or have as an ingredient or component, a GM food.[6] Standard 1.1.2 defines what is a 'food produced using gene technology' (referred to generally as a 'GM food' in this report) for this purpose.[7]

The above in effect requires pre-market approval of a GM food before it can enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment by FSANZ.

Standard 1.5.2 sets out the permission and conditions for sale of a food that is, or has as an ingredient, a GM food. Permitted GM foods are listed in Schedule 26 of the Code. A GM food that is permitted for use as a food additive by Standard 1.3.1 or as a processing aid by Standard 1.3.3 is also a permitted GM food for the purposes of Standard 1.5.2.

Labelling

Standard 1.1.1 requires that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Section 1.5.2—4 requires a food for sale that consists of, or has as an ingredient, a food that is a *genetically modified food* to be labelled as 'genetically modified'.[8]

---

[5] See https://www.foodstandards.gov.au/consumer/gmfood/health-canada-fsanz-shared-assessment-process for more information.
[6] See paragraphs 1.1.1—10(5)(c) and 1.1.1—10(6)(g)
[7] See definition in subsection 1.1.2—2(3).
[8] 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).

A genetically modified food is a GM food that:

- contains novel DNA or novel protein, or
- is listed in subsections S26—3(2), (2A) or (3) (i.e. regardless of the presence of novel DNA or novel protein in the foods). The foods listed in these subsections 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.

Section 1.5.2—4 also provides that its labelling requirements do not apply if the genetically modified food:

- has been highly refined (other than food that has an altered characteristic), where the effect of the refining process is to remove novel DNA or novel protein
- is a substance used as a processing aid or a food additive and no novel DNA or novel protein from the substance remains present in the food for sale
- is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%)
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient, or
- 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.

The labelling requirements imposed by section 1.5.2—4 apply to the following in accordance with Standard 1.2.1:

- a food for retail sale. In the case where a food for retail sale is not required by the Code to bear a label and is not in a package, subsections 1.2.1—9(2) and (3) require labelling information prescribed in section 1.5.2—4 to accompany the food or be displayed in connection with the display of the food; or
- a food sold to a caterer. In the case where a food sold to a caterer is not required by the Code to bear a label, section 1.2.1—13 and paragraph 1.2.1—15(f) require information prescribed in section 1.5.2—4 to be provided to the caterer with the food.

1.4 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (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 tomato lines containing event Del/Ros1-N is provided in Supporting Document 1 (SD1) and includes the following key elements:

- a characterisation of the transferred genetic material, its origin, function and stability in the tomato 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 previous assessment reports on similar GM foods.

The assessment of tomato lines containing event Del/Ros1-N was restricted to human food safety and nutritional issues.

The applicant is currently seeking a licence from the GTR for the commercial cultivation of tomato lines containing event Del/Ros1-N in Australia. Risks to the environment that may occur as the result of growing tomato lines containing event Del/Ros1-N, or any risks to animals that may consume feed derived from tomato lines containing event Del/Ros1-N, 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 tomato lines containing event Del/Ros1-N is as safe for human consumption as food derived from non-GM tomato varieties.

2.2 Risk management

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

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

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code to permit the sale and use of food derived from tomato lines containing event Del/Ros1-N.

2.2.1 Regulatory approval

Tomato lines containing event Del/Ros1-N are a GM food for Code purposes as they are derived from ‘an organism which has been modified by gene technology’. FSANZ is proposing to list tomato lines containing event Del/Ros1-N in the table to subsection S26—3(4) as well as in subsection S26—3(2). The listing in subsection S26—3(2) is because food derived from these tomato lines was determined to have altered characteristics (see Sections 5.4.1 and 6 of SD1). If approved, the amendment made by the draft variation would permit the sale and use of food derived from tomato lines containing event Del/Ros1-N as a GM food in accordance with the Code.

2.2.2 Labelling

2.2.2.1 Requirements for labelling as 'genetically modified'

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 tomato lines containing event Del/Ros1-N, 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), (2A) 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 all three novel proteins (Del, Ros1 and NPTII) are expressed at undetectably low levels in Del/Ros-N purple tomatoes, indicating exposure to the proteins from consumption of the purple tomato would be negligible (see Section 4 of SD1). However, it is probable that novel DNA would be present in many tomato products for sale derived from tomato lines containing event Del/Ros1-N.

FSANZ has determined that food derived from tomato lines containing event Del/Ros1-N has altered characteristics. The compositional analysis indicates that compared to non-GM counterparts, these GM tomato varieties contain elevated levels of anthocyanins and chlorogenic acid (CGA) (see Sections 5.4.1 and 6 of SD1).

Fresh, whole tomatoes and processed food products derived from tomato lines containing event Del/Ros1-N (e.g. purees, concentrates and juices) would require labelling as 'genetically modified', unless an exemption applies (see below). The labelling statement would also apply to highly refined products (e.g. tomato extracts).

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

If the food for sale is not required to bear a label in accordance with section 1.2.1—9, 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 (paragraphs 1.2.1—9(3)(b) and (ba) and subsection 1.2.1—9(2)). The retail sale scenarios listed below are examples where this information requirement would apply to tomato lines containing event Del/Ros1-N:

- Unpackaged, fresh, whole tomatoes.
- Whole or cut fresh tomatoes when sold in a package that does not obscure the nature or quality of the food.
- A food product containing a tomato ingredient that is displayed in an assisted service display cabinet.

Existing labelling exemptions may apply in circumstances where:

- A flavouring substance derived from Del/ROS-N purple tomatoes is present in the food in a concentration of no more than 1 g of flavouring/kg of food (or 0.01 per cent) (paragraph 1.5.2—4(1)(c)).
- Del/ROS-N purple tomatoes are unintentionally present in the food in an amount of no more than 10 g in a kilogram (or 1 per cent) of each ingredient (paragraph 1.5.2—4(1)(d)).
- The food is intended for immediate consumption and prepared and sold from food

premises and vending vehicles, including restaurants, takeaway outlets, caterers or self-catering institutions (paragraph 1.5.2—4(1)(e)).

2.2.2.2 Need for additional labelling requirements

As noted above, tomato lines containing event Del/Ros1-N have altered characteristics when compared to non-GM tomatoes. That is, elevated levels of anthocyanins and of CGA.

Labelling of GM food is intended to address the objective set out in paragraph 18(1)(b) of the FSANZ Act—the provision of adequate information relating to food to enable consumers to make informed choices. For this reason, FSANZ considered whether additional labelling (i.e. in addition to the mandatory 'genetically modified' statement described above) is required to alert consumers to these altered characteristics.

FSANZ has not proposed additional mandatory labelling because:

- The increased levels of anthocyanins and CGA are not biologically significant and do not raise any safety concern (see sections 5 and 6 of SD1).
- Tomatoes from tomato lines containing event Del/Ros1-N will have deep purple skin and flesh from the presence of anthocyanins. Consumers will be able to distinguish them from non-GM red tomatoes by their appearance and the required 'genetically modified' statement. While there are purple tomato varieties currently in the marketplace that are non-GM, these are uncommon, do not contain homogenous deep purple skin and flesh and would not be labelled as 'genetically modified'.
- FSANZ considers that labelling for the change in the levels of anthocyanins or CGA would be unlikely to provide consumers with meaningful information. Anthocyanins and CGA are minor constituents that are naturally present in high amounts in other commonly consumed foods (e.g. cherry, blueberry, strawberry and purple potato) compared to GM Purple Tomato (see sections 5.4.1, 5.5 and 6 of SD1). Other than the appearance of the skin and flesh, increases in the amounts of anthocyanins and CGA do not change the nature of the food and consumers are unlikely to know what these substances are. In this context, additional labelling is likely to be confusing and potentially misleading to consumers.
- Existing requirements to label food as 'genetically modified' would apply to ensure consumers can make informed choices.

2.2.2.3 Voluntary representations made about food

Standard 1.2.7 (Nutrition, health and related claims) sets out the requirements for nutrition content and health claims about a food or a property of food[9] and conditions for making such claims are set out in Schedule 4. The term 'claim' is also defined in the Code.[10]

Neither the category name 'anthocyanins' nor the specific anthocyanins present in the GM Purple Tomato are listed in section S4—3. Nutrition content claims about properties of food not listed in section S4—3 may state only that the food contains or does not contain the property of food and/or that the food contains a specified amount of the property of food in a specified amount of that food (subsection 1.2.7—13).

The application states that dietary anthocyanins are associated with reduced risk of chronic and degenerative diseases such as cardiovascular disease, obesity and certain cancers. However, the application also states that neither the applicant nor its partners intend making explicit health claims about anthocyanins.

[9] **Property of food** means a component, ingredient, constituent or other feature of food (subsection 1.1.2—2(3)).
[10] **Claim** means an express or implied statement, representation, design or information in relation to a food or a property of food which is not mandatory in this Code (subsection 1.1.2—2(3)).

Should suppliers wish to make a health claim, the requirements for making a high level health claim[11] or a general level health claim[12] are provided in Division 5 of Standard 1.2.7. Conditions for making such claims are set out in section S4—4 and section S5—5 of Schedule 4, respectively. There are no pre-approved health claims relating to anthocyanins in either of these sections. A self-substantiation pathway exists for making a general level health claim in accordance with requirements in Division 5 and Schedule 6. However, high level health claims must be based on a pre-approved food-health relationship in section S5—4. More information about the requirements for nutrition content and health claims is available on FSANZ's website[13].

Representations made about a food derived from tomato lines containing event Del/Ros1-N would also be subject to other Australian and New Zealand consumer protection legislation designed to prevent misleading or deceptive conduct, including in relation to food.

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-Committee[14] 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[15] based detection method. This sequence information was supplied by the applicant for A1333.

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 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 the draft variation.

The draft variation will be considered by the FSANZ Board taking into account all public comments received through this call for submissions.

The applicant, individuals and organisations that make submissions on this application will be notified at each stage of the assessment.

[11] **High level health claim** means a health claim that refers to a serious disease or a biomarker of a serious disease (subsection 1.1.2—2(3)).
[12] **General level health claim** means a health claim that is not a high level health claim (subsection 1.1.2—2(3)).
[13] https://www.foodstandards.gov.au/business/labelling/nutrition-health-and-related-claims.
[14] Now known as the Implementation Subcommittee for Food Regulation.
[15] Polymerase Chain Reaction.

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 not substantially the same as existing 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 tomato lines containing event Del/Ros1-N 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 is 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

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA). Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for applications relating to GM food. 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 their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

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

The purpose of this consideration is to determine if the community, government or industry as a whole is likely to benefit, on balance, from a move from the status quo, where status quo is rejecting the application. This analysis considers permitting the sale and use of food derived from tomato lines containing event Del/Ros1-N.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo by permitting the sale and use of food derived from tomato lines containing event Del/Ros1-N.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

Consideration of costs and benefits of permitting the sale and use of food derived from tomato lines containing event Del/Ros1-N

The sale of foods derived from tomato lines containing event Del/Ros1-N would be permitted under the Code, allowing broader market access and increased choice. Due to the voluntary nature of the permission, manufacturers and retailers would only use foods derived from tomato lines containing event Del/Ros1-N where they believe a net benefit exists for them. Part of any cost savings experienced by the food industry may be passed onto consumers.

For those food products derived from tomato lines containing event Del/Ros1-N, existing GM labelling requirements would apply to assist consumers wishing to avoid these products.

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

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the sale and use of food derived from tomato lines containing event Del/Ros1-most likely outweigh the associated costs.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure 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

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

FSANZ 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 tomato lines containing event Del/Ros1-N. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ’s assessment is that food derived from tomato lines containing event Del/Ros1-N is as safe for human consumption as food derived from other conventional non-GM tomato varieties.

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 tomato lines containing event Del/Ros1-N, in accordance with the Code to enable informed consumer choice (see section 2.2.2).

2.5.2.3 The prevention of misleading or deceptive conduct

No issues were identified that are relevant to 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, 2009). Based on these principles, the risk analysis undertaken by FSANZ for tomato lines containing event Del/Ros1-N used the best scientific evidence available. The applicant submitted a comprehensive dossier of scientific data. In addition, other data 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 safe GM foods in the food supply allows for innovation by product developers and a widening of the technological base for producing foods. The GM Purple Tomato is a new food designed to provide an additional choice for consumers.

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

Issues related to consumer information and safety are considered in sections 2.1, 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 draft variation to the Code is at Attachment A and is intended to take effect on 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 A1333 – Food derived from purple tomato lines containing event Del/Ros1-N) 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]

[Insert name and position of Delegate]
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 A1333 – Food derived from purple tomato lines containing event Del/Ros1-N) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 26—Food produced using gene technology

[1] Subsection S26—3(2) (not including the note)

Repeal the subsection, substitute:

(2) Items 1(g), 1(i), 2(m), 7(e), 7(g), 7(h), 9(a) and 12(a) of the table to subsection (4) are subject to the condition that their labelling must comply with section 1.5.2—4.

[2] Subsection S26—3(4) (table item 11)

Repeal the item, substitute:

11	**Banana**	(a)	disease-resistant banana line QCAV-4
12	**Tomato**	(a)	purple tomato lines containing event Del/Ros1-N

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1333 – Food derived from purple tomato lines containing event Del/Ros1-N) 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 A1333 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) – tomato lines containing event Del/Ros1-N (the GM Purple Tomato). The GM Purple Tomato has been genetically modified for purple fruit colour. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1333 – Food derived from purple tomato lines containing event Del/Ros1-N) Variation* (the draft 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 sunsetting 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 sunsetting 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 sunsetting 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 a draft variation amending the table to subsection S26—3(4) in Schedule 26 of the Code to permit the sale and use of food derived from tomato lines containing event Del/Ros1-N, in accordance with the Code.

4. Documents incorporated by reference

This 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 A1333 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-week period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA).[16] Impact analysis is no longer required to be finalised with the OIA. Prior to those changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for applications relating to GM foods, updated OIA reference: **OIA23-06225**. 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 their use will be voluntary if the draft variation relating 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

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

References to the 'variation' in this section are references to the draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1333 – Food derived from purple tomato lines containing event Del/Ros1-N) Variation*.

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

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

Items [1] and [2] of the Schedule to the variation would amend Schedule 26.

Item [1] would amend Schedule 26 by repealing and replacing subsection S26—3(2) (not including the note to this subsection). The text of the new subsection S26—3(2) includes a reference to item 12(a) of the table to subsection S26—3(4). The effect of this change would be to require a food for sale derived from purple tomato lines containing event Del/Ros 1-N to

[16] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

comply with the labelling requirement imposed by section 1.5.2—4 of the Code.

The existing note to subsection S26—3(2) would remain. This note explains to the reader that section 1.5.2—4 of the Code requires the statement 'genetically modified'.

Item [2] would amend Schedule 26 by repealing and replacing item 11 in the table to subsection S26—3(4) with a new item 11 and a new item 12.

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

New item 11 restates the existing item 11 in that table.

New item 12 would consist of the following entries:

- column 1 ('***Commodity***') – references to '12' as the new item number and 'Tomato' as the new commodity; and
- column 2 ('***Food derived from***') – a reference to '(a) purple tomato lines containing event Del/Ros1-N' as a permitted GM food.

If the draft variation is approved, the effect of this amendment would be to permit the GM Purple Tomato to be a food for sale and the sale of foods that contain the GM Purple Tomato as an ingredient, subject to any conditions set by the Code (such as in relation to labelling).