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368-25

Approval report – 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 and use of food derived from purple tomato lines containing event Del/Ros1-N.

On 30 July 2025, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 32 submissions.

FSANZ approved the draft variation on 29/10/2025. The Food Ministers' Meeting¹ was notified of FSANZ's decision on 10/11/2025.

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

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Supporting document

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

SD1 Safety assessment report – at approval

The published submissions from the call for submissions can be found on the [A1333 Consultation Hub](#) page.

¹ A1333 webpage – <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 assessed an application from Norfolk Healthy Produce Inc. seeking a variation of Schedule 26 in the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of 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.

As stated in section 18 of the *Food Standards Australia New Zealand Act 1991*, the primary objective of FSANZ in developing or varying a food regulatory measure is the protection of public health and safety. Accordingly, a safety assessment is a critical part of the assessment and approval process for all GM food applications.

Our safety assessment for the GM Purple Tomato, based on the best available scientific evidence, found no potential public health and safety concerns. Food derived from the purple tomato lines is as safe for human consumption as food derived from conventional tomato varieties.

Existing labelling requirements for GM food will apply to food derived from the purple tomato lines in accordance with the Code. Food derived from the purple tomato lines will be required to be labelled as 'genetically modified' regardless of whether it contains novel DNA or novel protein, because it has altered characteristics.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 30 July 2025. Thirty-two submissions were received in the six-week consultation period. FSANZ has had regard to all submissions.

For reasons set out in this report, FSANZ has decided to approve the draft variation proposed at the call for submissions with minor amendments. The approved draft variation will amend Schedule 26 of the Code to add a new item 12 in the table to subsection S26—3(4), which will contain a reference to 'tomato lines containing event Del/Ros1-N'. The effect of the approved draft variation will be to permit the sale and use of food derived from the purple tomato lines in accordance with the Code. The approved draft variation will also amend subsection S26—3(2) to require a food for sale that contains or consists of food derived from the purple tomato lines to be labelled as 'genetically modified'.

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 GM Purple Tomato, or the purple tomato lines). 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	<i>Del</i> (<i>Delila</i>)	<i>Antirrhinum majus</i> (snapdragon)	Transcription factor (anthocyanin biosynthesis)	No
Ros1	<i>Ros1</i> (<i>Rosea1</i>)	<i>A. majus</i>	Transcription factor (anthocyanin biosynthesis)	No
NPTII	<i>nptII</i>	<i>Escherichia coli</i>	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 need to consult the EPA and seek advice from the Ministry for Primary Industries (MPI)⁴ in relation to biosecurity requirements.

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 food for sale to comply with the Code. The

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/>

⁵ See <https://www.foodstandards.gov.au/consumer/gmfood/health-canada-fsanx-shared-assessment-process> for more information.

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 'genetically modified food' (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.

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 contains, or consists of, a GM food that is listed in Schedule 26 to be labelled as 'genetically modified', where that GM food:

- contains novel DNA or novel protein in accordance with subparagraph 1.5.2—4(1)(b)(i), or
- is listed in section S26—3 as being subject to a condition that its labelling must comply with section 1.5.2—4. Subsections S26—3(2) and (2A) of Schedule 26 list certain GM foods to which the labelling condition in subparagraph 1.5.2—4(1)(b)(ii) applies. These GM 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 a GM food. Subsection S26—3(3) of Schedule 26 requires a labelling statement to apply to a certain GM food if a specific condition is met.

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

- contains a GM food that is unintentionally present in an amount of no more than 10 g/kg (or 1%) of each ingredient
- is intended for immediate consumption and is prepared and sold from food premises including restaurants, take away outlets, caterers, self-catering institutions and vending vehicles.

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

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).

information prescribed in section 1.5.2—4 to be provided to the caterer with the food. The labelling information prescribed in section 1.5.2—4 is the statement ‘genetically modified’ used in conjunction with the name of the GM food (see subsection 1.5.2—4(3)).

1.4 Regulatory submissions to other countries

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

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	Approved
	Canadian Food Inspection Agency (CFIA)	Cultivation	Approved
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

1.5 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.

1.6 Procedure for assessment

The application was assessed under the General Procedure.

1.7 Decision

For reasons outlined in this report, FSANZ decided to approve the draft variation proposed at the call for submissions with the following amendments:

- amend the title of Schedule 26 listed in the Schedule to the draft variation to refer to ‘Genetically modified food’ instead of “Food produced using gene technology”, to account for amendments made to the Code resulting from Proposal P1055 – *Definitions for gene technology and new breeding techniques* - which came into effect on 2 September 2025,
- amend item [2] of the Schedule to the draft variation to:
 - (i) add the text ‘(see subsection (2))’ to new item 12 in the table to subsection S26—3(4), for consistency with other entries in Schedule 26 with altered characteristics; and

- (ii) change the text being inserted into the above-mentioned table to avoid creating a formatting error in the Code.

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.

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions (CFS) on a proposed draft variation to the Code on 30 July 2025. The consultation period was six weeks.

A total of 32 submissions were received. The submissions are publicly available on the FSANZ website [A1333 Consultation Hub](#) page.⁸

Of the 32 submissions, 25 opposed the draft variation. Submissions opposing the draft variation were received from:

- 21 private individuals
- GE Free NZ
- GeneEthics Ltd
- The Soil and Health Association of New Zealand
- Choice Farms

The 7 submissions supporting the proposed draft variation were received from:

- 5 private individuals
- New South Wales Food Authority (NSWFA)
- New Zealand Food Safety (NZFS)

NSWFA and NZFS 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 tomato lines containing event Del/Ros1-N is safe for human consumption. Individuals in favour of the proposed draft variation indicated general support for GM foods, as well as specific support for the GM Purple Tomato.

Many of the submissions received by FSANZ raised issues that are outside FSANZ's regulatory remit. These included issues related to the environment, crop development and agricultural practices. FSANZ directs submitters who would like more information about the environmental impact of GM Purple Tomato to see the OGTR's [risk assessment and risk management plan](#).⁹ Responses to other issues are provided in Table 3.

⁸ A1333 Consultation Hub page – <https://consultations.foodstandards.gov.au/fsanz/a1333-del-ros1-n-purple-tomato/>

⁹ Risk assessment and risk management plan for DIR218 is available here – <https://www.ogtr.gov.au/gmo-dealings/dealings-involving-intentional-release/dir-218>

Table 3: Summary of issues

Issue	Raised by	FSANZ response
Safety		
No human trials of the GM Purple Tomato have been undertaken, and there is an absence of long-term consumption studies to assess potential health effects.	GE Free NZ; GeneEthics; Soil & Health; Private Individuals (LMG, YM, CAS, JES, SJL)	Noted. FSANZ's safety assessment of the GM Purple Tomato was conducted in accordance with internationally established scientific principles and guidelines developed through the work of the Organisation for Economic Cooperation and Development (OECD), Food and Agriculture Organization (FAO) of the United Nations, World Health Organization (WHO) and the Codex Alimentarius Commission. Under these guidelines, the evaluation of GM foods focusses on molecular characterisation, compositional analysis, and evaluation of potential toxicity or allergenicity. Based on a comprehensive review of the available scientific data, FSANZ concluded that the GM Purple Tomato is as safe and nutritious as conventional tomato varieties. In the absence of identified hazards, human trials and long-term studies are unnecessary. FSANZ considers the potential for long-term risks to be no greater than for conventional tomatoes already in the food supply.
There is insufficient evidence to rule out the formation of new allergens or toxins. There is an increased potential for allergenic risks in sensitive individuals (including cross-reactivity of tomato with birch pollen).	Private individual (LJ)	Noted. FSANZ's safety assessment considered whether the genetic modification found in the GM Purple Tomato could lead to the production of new allergens or toxins (see sections 3 and 4 of SD1). The assessment concluded that no new proteins with similarities to allergens or toxins were generated as a result of the genetic modification. Allergy sensitive individuals are therefore not expected to be at increased risk of allergic reactions due to the genetic modification.

FSANZ has not been provided with genomic, metabolomic or epigenomic data to evaluate potential off-target effects. The genetic modification could have epigenetically altered ripening pathways, potentially affecting the detoxification of natural tomato toxins such as steroidal glycoalkaloids.	GE Free NZ; Private individual (JD)	Noted. FSANZ's safety assessment of the GM Purple Tomato did not identify any evidence suggestive of off-target or unintended changes in the GM Purple Tomato that would raise safety concerns. Additional genomic, metabolomic or epigenomic data are not considered necessary to establish the safety of GM foods. The accumulation of anthocyanins in the GM Purple Tomato does suppress processes involved in ripening (Zhang et al. 2013). However, this is not in itself a safety concern. The compositional data provided for the GM Purple Tomato included α-tomatine, the major steroidal glycoalkaloid in tomatoes. The levels of α-tomatine were found to be within the range observed for conventional tomato varieties (see section 5 of SD1).
<i>Compositional analysis and anthocyanin content</i>		
One submitter queried whether the safety assessment investigated the levels of all substances produced as a result of the upregulation of the anthocyanin biosynthesis pathway.	NSWFA	Noted. FSANZ's assessment was based on risk analysis and used the best available scientific evidence. That evidence included published data which investigates the metabolic profile of Del/Ros1-N purple tomatoes relative to a non-GM control (Toghe et al. 2015). This data reveals changes (up- or down-regulation) in numerous secondary metabolites. However, given these secondary metabolites are expressed at very low levels, an assessment of every metabolite was not considered necessary.
Submitters raised concerns about the safety of anthocyanins and chlorogenic acid (CGA), noting variability in their levels in the GM purple tomato across different genetic backgrounds and environmental conditions. One submitter was concerned that expressed anthocyanins have not been evaluated for their inhibition of mineral absorption.	Private individual (LMG); GeneEthics; Soil & Health; GE Free NZ	Noted. The levels of anthocyanins and CGA found in the GM Purple Tomato are addressed in sections 5 and 6 of SD1. Neither anthocyanins nor CGA have been linked to adverse health effects at the levels consumed in food. The only evidence for inhibition of mineral absorption by anthocyanins has been in studies involving high-dose supplementation. FSANZ considers that the levels of anthocyanins and CGA in the GM Purple Tomato do not raise safety concerns and are consistent with normal dietary exposure from other foods.

The safety assessment reports that there were significant differences between the GM Purple Tomato and the non-GM control in 9 of the 26 analytes evaluated, and expressed concern that the analytes evaluated represent a small subset of the total metabolites present in tomato.	GE Free NZ	Noted. Though statistically significant differences were found between the GM Purple Tomato and the non-GM control for 9 of the analytes tested, these differences were assessed as not biologically meaningful given the normal biological variability found in tomatoes (see Section 5 of SD1). FSANZ applies a targeted approach to compositional analysis in its safety assessment of GM foods, in line with internationally established scientific principles and guidelines. The analysis of every constituent in a given food is impractical and unnecessary. The focus of the assessment is on the key constituents that are most relevant to the overall diet and which may be significant to health and safety. In the case of the GM Purple Tomato, the constituents evaluated were consistent with those identified as key constituents in the <i>OECD Consensus Document on Compositional Considerations for New Varieties of Tomato</i>.¹⁰
Labelling		
These submitters raised the following concerns: • Purple tomato would not be labelled 'genetically modified' • Consumers will have no way of knowing if the food they buy, has been genetically altered. • The absence of labelling affects consumers' ability to make informed choices, which violates consumer autonomy. • Clear labelling won't be guaranteed for unpackaged products. • Mandatory or transparent labelling may not be ensured in New Zealand. • There are exemptions from mandatory labelling requirements.	Private individuals (JG)(LMG)(LJ) (S JL)	Noted. As noted in the CFS (and in section 2.3.2 of this report), GM Purple Tomato will be labelled 'genetically modified' unless an existing exemption applies (see below for FSANZ's response relating to the labelling exemption for food sold in a restaurant or takeaway outlet). The GM labelling requirement applies to packaged products that are GM Purple Tomato or which contain GM Purple Tomato as an ingredient. If the food is sold unpackaged (e.g. whole, fresh tomatoes in a bulk bin) or is not required to bear a label (e.g. a food sold in an assisted service display cabinet), this information must be stated in labelling that accompanies the food or is displayed in connection with the display of the food. Excepting the labelling exemption mentioned above, these existing labelling requirements ensure consumers are provided with information to make informed choices and apply to GM food sold in Australia and New Zealand. Further information is available from the FSANZ website.¹¹

¹⁰ OECD Consensus Document on Compositional Considerations for New Varieties of Tomato: Key Food and Feed Nutrients, Toxicants and Allergens: [https://one.oecd.org/document/ENV/JM/MONO\(2008\)26/en/pdf](https://one.oecd.org/document/ENV/JM/MONO(2008)26/en/pdf)

¹¹ GM labelling webpage – <https://www.foodstandards.gov.au/consumer/gmfood/labelling>

This submitter noted their objection to GM products not being openly advertised. They stated this was a deceptive practice and it is important for a consumer to know basic information relating to the way a plant has been grown.	Private individual (KC)	Noted. Please see response above. A food for sale containing or consisting of a permitted GM food that contains novel DNA, novel protein or altered characteristics (ie, listed in subsection S26—3(2)) must be labelled as ‘genetically modified’ unless an existing Code exemption applies. See section 2.3.2 of this report. This Code requirement is applied by and forms part of Australian and New Zealand food laws. The existing labelling requirements are ‘product-based’, which means labelling is based on the GM food for sale being analytically different from non-GM counterpart food. The regulatory approach reflects the policy set by food ministers in 2000 and was reaffirmed in 2011. The approach is based on providing meaningful information for informed consumer choice in most retail sale scenarios while being practical and enforceable.
This submitter stated that open, fair, and evidence-based customer information on anthocyanins must be mandated to prevent unsubstantiated health claims and imputations in advertising, on labels, and in other public communications.	GeneEthics	Noted. FSANZ’s assessment is that additional labelling requirements in relation to anthocyanins are not warranted for the reasons set out in section 2.3.2.2 and of 2.3.2.3 of this report. As noted in the CFS (and in section 2.3.2.3 of this report), suppliers wishing to make voluntary representations about food must comply with claim requirements in the Code and will also be subject to consumer protection legislation that prevents misleading or deceptive conduct.
One submitter noted that while it may not be too difficult for consumers to avoid buying the GM Purple Tomato as fresh produce, it may be harder to avoid it if it’s included as an ingredient. New Zealand’s GE labelling laws are already inadequate for consumers to make informed choices about avoiding GE food ingredients. For example, GE ingredients do not have to be labelled in restaurants and other food service outlets, so if the Purple Tomato is served fresh or as an ingredient in a	Soil & Health; Private individual (CAS)	Noted. The existing regulatory approach includes a labelling exemption for approved GM food sold in restaurant and takeaway meals (and by caterers and self-catering institutions). The labelling exemption recognises that food businesses may need to make substitutions because ingredients vary from time to time. See the FSANZ website¹² for further information. The state and territory food acts and the New Zealand Food Act 2014¹³ have general provisions which prohibit a food business from supplying food by way of sale if it is not of the nature or substance demanded by the purchaser. Food businesses must respond truthfully if a consumer asks about the product at the point of sale, including whether ingredients used are from a GM source. These provisions enable consumers to obtain information they require to make a purchasing decision.

¹² <https://www.foodstandards.gov.au/consumer/gmfood/labelling>

¹³ See Division 4 of Standard 1.1.1 of the Code.

processed product or meal it would not need to be labelled, making it harder for consumers to try to avoid. Another submitter noted the labelling exemption for GM Purple Tomatoes if they are used in restaurant or takeaway meals, or by caterers or self-catering institutions.		
NSW Food Authority concurs with FSANZ that representation of food derived from the GM purple tomato must be compliant with the Code as well as the Australian Consumer Law. With regard to the application of section 1.2.7—13, NSW Food Authority requests clarity from FSANZ if any substances produced in the anthocyanin biosynthesis pathway including anthocyanins are 'biologically active substances', as described in the definition of nutrition content claim in the Code.	NSWFA	Noted. Subsection 1.1.2—2(3) of the Code defines 'biologically active substance' to mean <i>a substance, other than a nutrient, with which health effects are associated</i>. Subsection 1.1.2—2(3) also defines 'health effect' to mean an effect on the human body, including an effect on one or more of the following: (a) a biochemical process or outcome; (b) a physiological process or outcome; (c) a functional process or outcome; (d) growth and development; (e) physical performance; (f) mental performance; (g) a disease, disorder or condition. As noted in section 5.4 of SD1 to the CFS, anthocyanins, chlorogenic acid and rutin are products and metabolites of the phenylpropanoid biosynthesis pathway. They are types of polyphenols that are deemed to have antioxidant properties and other potential health benefits. To the extent the latter are a health effect as defined by the Code, these substances would appear to be captured as biologically active substances for the purposes of the nutrition content and health claims framework.
Terminology		
One submitter asked that FSANZ clarify that the GM purple tomato meets the new definition of <i>genetically modified food</i> in Standard 1.5.2 following the gazettal of Proposal P1055, because it contains novel DNA.	NSWFA	As the GM Purple Tomato contains novel DNA in its genome, it meets the new definition for <i>genetically modified food</i> in Standard 1.5.2. See section 2.3.1 of this report.
One submitter queried the naming approach for the GM Purple Tomato, noting it is based on the event Del/Ros1-N, whereas other entries in subsection S26—3(4) of the Code refer to unique line(s). They recommended the term 'event' be replaced with 'transformation event', as this is the term defined in Schedule	NSWFA	The name '<i>Food derived from purple tomato lines containing event Del/Ros1-N</i>' reflects the information provided in the application and aligns with how the genetic modification was characterised and assessed. The term 'event' refers to the specific genetic modification that has been evaluated. While the term 'transformation event' is defined in Schedule 26, FSANZ considers 'event' is sufficiently clear within the context of the associated assessment and reports.

26.		
This submitter queried whether the proposed listing would exclude outcrosses with conventional tomato varieties which do not contain novel DNA, and expressed the view that the definition for 'line' in Schedule 26 is ambiguous with respect to null segregants.	NSWFA	FSANZ notes that, by definition, a null segregant does not contain novel DNA. If a tomato line containing event Del/Ros1-N is crossed with a conventional tomato variety, any progeny that have inherited the novel DNA would be a GM food and fall under the Schedule 26 permission. Alternatively, any progeny that do not inherit the novel DNA would be null segregants and not be a GM food. The definition for 'line' in Schedule 26 with respect to null segregants is irrelevant.
One submitter recommended adding '(see subsection (2))' after the proposed name for consistency with other permitted foods in Schedule 26 with altered characteristics.	NSWFA	FSANZ agreed with this recommendation. Refer to section 1.7 of this report.
Process		
One submitter stated that the separate assessments by FSANZ and the OGTR are a fundamentally flawed regulatory approach which does not allow for the integrated evaluation of environmental and food safety risks.	Private individual (JD)	FSANZ and the OGTR operate under distinct legislative frameworks, each with specific objectives and risks to be managed. The OGTR assesses environmental and human health risks associated with the intentional release of live and viable genetically modified organisms under the <i>Gene Technology Act 2000</i> and its associated regulations. In contrast, FSANZ is responsible for assessing the safety of GM foods under the Code, which forms part of broader food legislation in both Australia and New Zealand. In their assessments, each agency addresses the risks relevant to its legislative mandate: the OGTR considers broader biosafety and environmental risks, while FSANZ focuses specifically on issues relating to food. This division ensures that all relevant risks are assessed by the appropriate authority and there are no gaps in regulatory oversight.
One submitter expressed the view that FSANZ's assessment of the GM Purple Tomato breaches the legislative objectives of the FSANZ Act by not including <i>in vivo</i> nutrition studies and relying on applicant-provided data.	GE Free NZ	FSANZ does not agree. The safety assessment of the GM purple tomato was conducted in accordance with the legislative objectives of the FSANZ Act and international best practice and considered the best available scientific evidence. The assessment did not identify any new or altered hazards. In the absence of any identifiable hazards, additional studies such as <i>in vivo</i> nutrition studies are not warranted. It is standard regulatory practice to assess data provided by applicants, supported by independent scientific literature and general technical information.
Other issues		
Concerns about segregation costs or market penalties for non-GM and organic growers and retailers.	GeneEthics	Noted. FSANZ has previously commented on this issue under Proposal P1055 – new definitions for gene

		technology and new breeding techniques. Please refer to section 6.1 of the P1055 Approval Report ¹⁴ and section 5.5 of the Decision Regulation Impact Statement ¹⁵ for further detail.
Several submitters expressed views reflecting general opposition to GM foods.	Private individuals	Noted. FSANZ notes that GM foods have been part of the food supply for over 25 years. FSANZ's safety assessments of GM foods, which are based on risk analysis using the best available scientific evidence, ensure that all approved GM foods are as safe as their conventional counterparts. Further information about GM food safety assessment is available on the FSANZ website.¹⁶
Several submitters raised concerns about the potential impact of the GM Purple Tomato on the environment.	Private individuals	Noted. Issues relating to the environment are outside FSANZ's regulatory remit. The OGTR is considering potential environmental risks as part of their assessment of the GM Purple Tomato. You can find more information about the OGTR's assessment on the OGTR website.¹⁷

¹⁴ P1055 Approval Report – https://www.foodstandards.gov.au/sites/default/files/2025-06/01_P1055_Approval%20Report.pdf

¹⁵ P1055 Decision Regulation Impact Statement – <https://www.foodstandards.gov.au/sites/default/files/2025-06/P1055%20SD4%20Decision%20Regulation%20Impact%20Statement.pdf>

¹⁶ Safety assessments of GM foods - <https://www.foodstandards.gov.au/consumer/gmfood/safety>

¹⁷ DIR218 – Commercial release of tomato genetically modified for purple fruit colour – <https://www.ogtr.gov.au/gmo-dealings/dealings-involving-intentional-release/dir-218>

2.2 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 evidence 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, risks to animals that may consume feed derived from tomato lines containing event Del/Ros1-N, and risks to workers contacting or inhaling plant material 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, FSANZ's safety assessment concluded that food derived from tomato lines containing event Del/Ros1-N is as safe for human consumption as food derived from non-GM tomato varieties.

2.3 Risk management

Following assessment, FSANZ prepared a draft variation of the Code and called for submissions on that draft variation.

The risk management options available to FSANZ following the call for submissions were to:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

Having regard to the submissions received and for the reasons set out in this report, FSANZ has decided to approve the draft variation proposed following assessment with minor amendments (see Attachment A).

Risk management considerations for this application relating to the regulatory approval, labelling and detection methodology are discussed below.

2.3.1 Regulatory approval

Tomato lines containing event Del/Ros1-N are a GM food for Code purposes as they are derived from an organism that contains novel DNA. The approved draft variation lists tomato lines containing event Del/Ros1-N in the table to subsection S26—3(4) and includes a reference to that listing in subsection S26—3(2). The reference to that listing in subsection S26—3(2) was included because food derived from these tomato lines was determined to have altered characteristics (see sections 5.4.1 and 6 of SD1). The amendment made by the approved draft variation will 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.

2.3.2 Labelling

2.3.2.1 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, 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 section S26—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/Ros1-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 will be present in many tomato products for sale derived from tomato lines containing event Del/Ros1-N. If so, those foods for sale would need to be labelled as ‘genetically modified’ on that basis.

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). For that reason, the approved draft variation will amend subsection S26—3(2) to provide that the permission listed in the table to subsection S26—3(4) for the GM purple tomato is subject to the labelling requirement imposed by section 1.5.2—4.

The above means that fresh, whole tomatoes and processed food products derived from tomato lines containing event Del/Ros1-N (e.g. purees, concentrates, juices and extracts) will require labelling as ‘genetically modified’, unless an exemption applies (see below).

The label statement ‘genetically modified’ must be made in conjunction with the name of the GM food (subsection 1.5.2—4(3)). If the GM food is present as an ingredient (including an ingredient of a compound ingredient) in a packaged food for sale, this statement may appear in the label other than in the statement of ingredients (see subsection 1.5.2—4(4) for the requirement and paragraph 1.2.1—8(1)(k) for this requirement to apply to a packaged food).

If the food for sale is not required to bear a label because of section 1.2.1—6, then 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 will 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 would apply in circumstances where:

- Del/Ros1-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(2)(a)).
- The food is intended for immediate consumption and prepared and sold from food premises, including restaurants, takeaway outlets, caterers, self-catering institutions and vending vehicles (paragraph 1.5.2—4(2)(b)).

2.3.2.2 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 meaningful¹⁸ 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 relatively high amounts in other commonly consumed foods (e.g. cherry, blueberry, strawberry and purple potato) (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’ will apply to ensure consumers can make informed choices.

¹⁸ Changes in the amounts of these substances are not large or relevant in terms of biological function, health outcomes, or risk.

2.3.2.3 *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 food¹⁹ and conditions for making such claims are set out in Schedule 4. The term ‘claim’ is also defined in the Code.²⁰

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 to make explicit health claims about anthocyanins.

Should suppliers wish to make a health claim, the requirements for making a high level health claim²¹ or a general level health claim²² are provided in Division 5 of Standard 1.2.7. Conditions for making such claims are set out in section S4—4 and section S4—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 of Standard 1.2.7 and Schedule 6. However, high level health claims must be based on a pre-approved food-health relationship in section S4—4. More information about the requirements for nutrition content and health claims is available on FSANZ’s website²³.

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

2.3.3 **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-Committee²⁴ to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM food 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 PCR²⁵ based detection method. This sequence information was supplied by the applicant for A1333.

¹⁹ **Property of food** means a component, ingredient, constituent or other feature of food (subsection 1.1.2—2(3)).

²⁰ **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)).

²¹ **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)).

²² **General level health claim** means a health claim that is not a high level health claim (subsection 1.1.2—2(3)).

²³ <https://www.foodstandards.gov.au/business/labelling/nutrition-health-and-related-claims>.

²⁴ Now known as the Implementation Subcommittee for Food Regulation.

²⁵ Polymerase Chain Reaction.

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 development matters is open, accountable, consultative and transparent. Public submissions were invited on a draft variation released for public comment between 30 July 2025 and 10 September 2025. The CFS was notified via the FSANZ Notification Circular, media release and Food Standards News. Subscribers and interested parties were also notified.

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

Documents relating to A1333, including the submissions received, are available on the [FSANZ website](#).²⁶

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

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 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 as safe as conventional foods 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

²⁶ A1333 webpage – <https://www.foodstandards.gov.au/food-standards-code/applications/a1333-food-derived-purple-tomato-lines-containing-event-delros1-n>

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.

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

The sale and use of foods derived from tomato lines containing event Del/Ros1-N will be permitted under the Code, allowing broader market access and increased choice. Due to the voluntary nature of the permission, manufacturers and retailers will only sell and/or 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 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 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 tomato lines containing event Del/Ros1-N 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-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 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 tomato lines containing event Del/Ros1-N. Based on risk analysis and using 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 2.3.2).

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 2.2 and 2.3 above.

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

No specific policy guidelines have been developed.

3 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>

Tohge T, Zhang Y, Peterek S, Matros A, Rallapalli G, Tandrón YA, Butelli E, Kallam K, Hertkorn N, Mock HP, Martin C, Fernie AR. (2015) Ectopic expression of snapdragon transcription factors facilitates the identification of genes encoding enzymes of anthocyanin decoration in tomato. Plant J. 83(4):686-704

Zhang Y, Butelli E, De Stefano R, Schoonbeek HJ, Magusin A, Pagliarani C, Wellner N, Hill L, Orzaez D, Granell A, Jones JD, Martin C (2013) Anthocyanins double the shelf life of tomatoes by delaying overripening and reducing susceptibility to gray mold. *Curr Biol.* 23(12):1094-100

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

Attachment A – Approved 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—Genetically modified food

[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) (after table item 11)

Add:

12	Tomato	(a) purple tomato lines containing event Del/Ros1-N (see subsection (2))
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Attachment B – Explanatory Statement

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 purpose of Application A1333 was to amend the Code to permit the sale and use of food derived from a new genetically modified food (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 approved a draft variation – the *Food Standards (Application A1333 – Food derived from purple tomato lines containing event Del/Ros1-N) Variation* (the approved draft 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).

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 a draft variation to amend section S26—3 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; and require a food for sale derived from those purple tomato lines to comply with the labelling requirement imposed by section 1.5.2—4 of the Code.

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 A1333 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 30 July 2025 for a six-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA).²⁷ 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 as safe as conventional foods are considered to be minor and deregulatory in nature, as their use is voluntary. Under the new approach, FSANZ's assessment was that a regulatory impact statement was 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

References to the 'variation' in this section are references to the approved 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*.

²⁷ Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

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 amend Schedule 26.

Item [1] amends 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 new item 12(a) of the table to subsection S26—3(4).

The effect of this change is to require a food for sale derived from purple tomato lines containing event Del/Ros 1-N to comply with the labelling requirement imposed by section 1.5.2—4 of the Code.

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

Item [2] amends Schedule 26 by adding new item 12 in the table to subsection S26—3(4) after item 11 in that table.

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

New item 12 consists 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 ((see subsection (2))’ as a permitted GM food with an associated reference to subsection S26—3(2). Subsection S26—3(2) lists permitted GM food that must comply with the labelling requirement imposed by section 1.5.2—4 of the Code (see **item [1]** above).

The effect of this amendment is 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 or component, subject to any conditions set by the Code (such as in relation to labelling).

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)



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	(b) purple tomato lines containing event Del/Ros1-N