8 November 2024
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Approval report – Application A1289

Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25

Food Standards Australia New Zealand (FSANZ) has assessed an application made by SPS International Inc. seeking to amend the Australia New Zealand Food Standards Code to permit the sale and use of food derived from a new food produced using gene technology: potato line BG25. This potato line has been genetically modified to have disease-resistance, low-reducing sugars and reduced browning.

On 18 July 2024, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 30 October 2024. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 8 November 2024.

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

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website[2]:

SD1 Supporting Document 1 – Safety assessment report

[2] https://www.foodstandards.gov.au/food-standards-code/applications/a1289-food-derived-disease-resistant-low-reducing-sugars-and

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from SPS International Inc. seeking a variation to Schedule 26 in the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): potato line BG25. Potato line BG25 has been genetically modified (GM) to have disease-resistance to late blight and *Potato virus Y*, as well as low-reducing sugars and reduced browning.

As stated in section 18 of the *Food Standards Australia New Zealand Act 1991*, a 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 approval process for all GM food applications.

The safety assessment of potato line BG25 is in Supporting Document 1. The assessment found no potential public health and safety concerns. Based on the data provided by the applicant and other information, food derived from potato line BG25 is considered to be as safe for human consumption as food derived from conventional non-GM potato varieties.

Existing labelling requirements for GM food will apply to food derived from potato line BG25 in accordance with the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 18 July 2024. Four submissions were received in the six-week consultation period. FSANZ has had regard to these 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 to correct typographical and formatting errors. However, no change has been made to the risk management response proposed at the call for submissions. The approved draft variation will amend Schedule 26 of the Code to include a new paragraph (i) for item 5 in the table to subsection S26—3(4) containing a reference to ‘disease resistant, low-reducing sugars and reduced browning potato line BG25’. The effect of the approved draft variation will be to permit the sale and use of food derived from this potato line in accordance with the Code.

1 Introduction

1.1 The applicant

SPS International Inc. is a subsidiary of the United States of America (USA) food and agribusiness company J.R. Simplot Company, located in Boise Idaho, USA.

1.2 The application

Application A1289 was submitted on 12 December 2023. It seeks an amendment to the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): potato line BG25. This potato line has been genetically modified to have disease-resistance to late blight and *Potato Virus Y*, as well as low-reducing sugars and reduced browning. BG25 expresses 6 novel substances, summarised in Table 1.

Table 1: Novel substances expressed in BG25

Protein / novel substances	Gene	Donor organism	Function	Previously assessed by FSANZ?
R-protein VNT1	*Rpi-vnt1*	*Solanum venturii (wild potato*	Confers resistance against late blight disease	Yes (2 previous applications)
R-protein AMR3	*Rpi-amr3*	*Solanum americanum (American black nightshade)*	Confers resistance against late blight disease	No
R-protein BLB2	*Rpi-blb2*	*Solanum bulbocastanum (wild potato)*	Confers resistance against late blight disease	No
Modified acetolactate synthase (StmALS)	*StmAls*	*Solanum tuberosum (potato)*	Selectable marker	No (Assessed homologs of StmALS in 4 previous applications)
Vacuolar invertase (VLNV) / polyphenol oxidase (PPO) dsRNA	*Vlnv / Ppo inverted repeat*	*Vlnv - Solanum tuberosum and Ppo - Solanum verrucosum (wild potato)*	Confers the low-reducing sugars and reduced browning trait	Yes (2 previous applications)
PVY-Coat protein (CP) dsRNA	*PVY-CP inverted repeat*	*Potato Virus Y (PVY)*	Confers protection against PVY	Yes (1 previous application)

1.2.1 Safety assessment sharing with Health Canada

This is the third GM application assessed under the joint safety assessment sharing arrangement with Health Canada.

Extensive work undertaken in the early stages of the collaboration confirmed the compatibility of FSANZ's and Health Canada's safety assessment approaches, both in terms of how safety assessments are conducted and the conclusions that are reached. Both agencies also adhere to internationally agreed principles and guidelines for the conduct of GM food safety assessments developed by the Codex *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology (Codex, 2009a). This provides a strong basis for safety assessment sharing between the two agencies.

The goal of safety assessment sharing is to establish a system where a safety assessment is jointly prepared that meets the separate requirements of both agencies with each undertaking their own separate and independent approval process.

For potato line BG25 (the current application), the joint food safety assessment was initially prepared by FSANZ (SD1) and then provided to Health Canada for review and use as part of their approval process.

1.3 The current Standard

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.[3] Standard 1.1.2 defines what is a GM food for this purpose.[4]

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.

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. Standard 1.5.2 also provides 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'.[5]

A genetically modified food is a GM food that:

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[3] See paragraphs 1.1.1—10(5)(c) and 1.1.1—10(6)(g)

[4] See definition in subsection 1.1.2—2(3).

[5] Subsection 1.5.2—4(5) defines ***genetically modified food*** to mean 'a *food produced using gene technology that

a) contains novel DNA or novel protein; or
b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section' (*that being section 1.5.2—4*).

- contains novel DNA or novel protein; or
- is listed in subsections S26—3(2), (2A) and (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 requirement does 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%); or
- 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. Food for retail sale may include food that is not required by the Code to bear a label and is not in a package. In this case, subsections 1.2.1—9(2) and (3) require labelling information 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. Food sold to a caterer may include food that is not required by the Code to bear a label and is not in a package. In this case, section 1.2.1—13 and paragraph 1.2.1—15(f) require information 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 was assessed under the General Procedure.

1.6 Decision

For reasons set out in this report, the draft variation as proposed following assessment was

approved with minor amendments to correct typographical and formatting errors. The approved draft variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation to the Code on 18 July 2024. The consultation period was six weeks.

Four submissions were received of which one was confidential. One from New Zealand Food Safety (NZFS) – supported the proposed draft variation to Schedule 26 and did not raise any issues. The other two submissions, from a private individual and from Australian Organic Limited, opposed the proposed draft variation and raised a number of issues.

Some of the issues were outside the scope of FSANZ's regulatory remit. The issues raised included trade, the regulatory framework for gene edited products, and general opposition to GM foods not directly related to FSANZ's assessment of potato line BG25.

Responses to all issues raised in submissions are provided in Table 2.

Table 2: Summary of issues

Issue	Raised by	FSANZ response
These submitters raised one or more of the following safety concerns about potato line BG25: • Absence of long-term intergenerational human studies to assess the stability and cumulative exposure of the novel proteins and RNA interference (RNAi) on human health. • Independent studies must be conducted, particularly on vulnerable populations who may be more susceptible to adverse effects.	Australian Organic Limited; Private Individual	FSANZ notes these concerns. FSANZ has conducted a comprehensive safety assessment of the four novel proteins and two double-stranded RNA (dsRNA) molecules present in potato line BG25. The safety assessment did not identify any new or altered hazards. Please refer to section 4 of the Supporting Document 1 (SD1) for further details. In the absence of any new or altered hazards, additional studies on humans or in vulnerable populations, of any length, are not warranted and unlikely to contribute any further useful information to the safety assessment. Additional information on potential long-term risks or why FSANZ does not do its own independent testing of GM foods can be found on our website.[6]

[6] Safety assessments of GM foods – https://www.foodstandards.gov.au/consumer/gmfood/safety

Issue	Raised by	FSANZ response
Unintended effects of genetic modification e.g. introduction of allergens and toxins leading to adverse health effects. Absence of long term epidemiological studies leaves critical gap in understanding the true implications on human health.	Australian Organic Limited	FSANZ does not agree. The safety assessment of potato line BG25 evaluated both intended and unintended changes as a result of the genetic modification. It concluded there are no allergenic or toxicity concerns associated with the expressed novel proteins / dsRNA molecules. FSANZ directs the submitter to section 3.4.5 and 4 of the SD1. FSANZ notes the occurrence of unintended effects is not unique to genetic modification, but also occurs in conventional breeding. The accumulated evidence and regulatory experience over the last 25 years does not support the hypothesis that GM foods have a greater propensity for unintended effects or that the technology is itself inherently harmful or a major source of risk to the consumer, compared to conventional forms of breeding (Herman and Price 2013; Ricroch 2013; Ladics et al. 2015; Schnell et al. 2015; FSANZ 2019; FSANZ 2021). FSANZ adds, there is no credible scientific basis to support the notion that food allergies are linked to the commercialisation of any GM crops or that allergens can arise spontaneously as a result of the genetic modification process (Goodman and Tetteh 2011). Similarly, there is no evidence that toxins can arise spontaneously as a result of the genetic modification process (Bartholomaeus et al. 2013). In relation to an epidemiological study, FSANZ notes that many health effects have complex causes. It is unlikely observational epidemiological studies could establish causation against the background of health effects resulting from diets made up primarily of conventional foods.

Issue	Raised by	FSANZ response
The use of RNA interference (RNAi) technology to silence certain genes in potato line BG25 raises regulatory challenges. Traditional safety assessments may not fully address the potential of long-term impacts of these new substances, including their stability and interactions within the human body.	Australian Organic Limited	FSANZ does not agree. FSANZ's approach to assess the safety of GM food, both generally and for the purposes of this application, is based on core concepts and principles developed by the Codex Alimentarius Commission (Codex 2009a, 2009b). The assessment protocol has been subjected to scientific scrutiny and has proven to be a robust approach for whole food safety assessments. This approach is not unique to FSANZ, but has been widely adopted by governments around the world. The approach ensures that GM foods are as safe as their non-GM counterparts. FSANZ's safety assessment of the dsRNA molecules in BG25 did not identify any new or altered hazards. In their absence, studies that assess long-term impacts would not add value to the safety assessment and are not warranted. In relation to interactions within the human body, a history of safe human consumption of RNAi mediators exists, including those with homology to human genes. The evidence published to date also does not indicate that dietary uptake of such RNA from plant food is a widespread phenomenon in vertebrates (including humans) or, if it occurs, that sufficient quantities are taken up to exert a biologically relevant effect. Regarding stability, evidence indicates ingested RNA molecules undergo denaturation and degradation during the digestive process before being removed from the body. In some cases, smaller RNA molecules that may be absorbed into the bloodstream are shown to be degraded by the nucleases present in blood and rapidly cleared from the bloodstream. Please visit the FSANZ website[7] for further details.

[7] Regulation of GM crops and foods developed using gene silencing – https://www.foodstandards.gov.au/consumer/gmfood/Response-to-Heinemann-et-al-on-the-regulation-of-GM-crops-and-foods-developed-using-gene-silencing

Issue	Raised by	FSANZ response

This submitter expressed two concerns regarding horizontal gene transfer (HGT):
 	
• Infant gut microbiota is especially susceptible to HGT events, which could exacerbate the spread of antibiotic resistance genes.
 	
• The presence of modified acetolactate synthase (*Als*) gene which confers tolerance to imidazolinone herbicides raises concerns of HGT and its impact on gut microbiota. Though research has shown that HGT from plants to bacteria is low but it is not negligible.
	Australian Organic Limited	FSANZ notes the transfer of DNA from food products to gut microorganisms is regarded as a rare possibility because of the many complex and unlikely events that would need to occur consecutively.
		
		Regarding the specific concerns, FSANZ provides the following responses:
		
		• There are no antibiotic-resistance genes in potato line BG25. Refer to section 3.2 of the safety assessment report (SD1) for further details.
		
		• The modified *Als* gene present in BG25
		  ○ is 99% identical to the native *Als* gene already present in commonly consumed non-GM potato varieties (*S. tuberosum*). Therefore, humans are already exposed to the *Als* gene through consumption of conventional potato varieties.
		  ○ will most likely be broken down and degraded during the digestive process, just like any other DNA contained in our diet, eliminating the likelihood of HGT of the *Als* gene. In the highly unlikely event a fully functional copy of the gene is taken up by a gut microorganism, the absence of any positive selection pressure makes it unlikely the microorganism would be able to stably maintain the DNA. In the absence of a credible pathway to harm, potential impacts on gut microbiota or human health are considered unlikely.
		
		Further information on HGT can be found on the FSANZ website[8]. A recent publication by the Office of the Gene Technology Regulator provides an update on HGT (Philips et al. 2022).

[8] Safety assessment of GM foods – https://www.foodstandards.gov.au/consumer/gmfood/safety

Issue	Raised by	FSANZ response
This submitter expressed the following concerns regarding contamination of organic potato with GM potato. • Cultivation of GM potatoes like BG25 could jeopardise the organic market and trade for Australian organic producers. • The integrity of organic agricultural processes may be at risk from unintentional contamination of organic seed stock if GM potato BG25 is labelled as non-GM. • Organic producers face economic losses from GM contamination and legal uncertainty. • Presence of GM potato in the market could lead to consumer confusion and reduced trust in organic labelling due to failure in recognition of organic certification.	Australian Organic Limited	FSANZ notes these concerns and provides the following responses: • Matters related to cross-contamination of agricultural commodities and organic certification are outside FSANZ's remit. • The issue of unintentional contamination of organic seed stock, and potential economic losses that may result from such contamination, is not relevant to this application which relates only to the sale and use of food derived from a potato line intended for cultivation overseas. Foods from this potato line may enter Australia and New Zealand as imported processed foods products e.g. french fries, potato crisps, potato flour or potato starch. • Permission to cultivate potato line BG25 in or to import viable tubers into Australia or New Zealand would require separate regulatory assessment and approval by the Gene Technology Regulator (GTR)[9] in Australia or by the Environmental Protection Authority (EPA)[10] in New Zealand respectively. Refer to section 2.2 of this report for further details. • Potato line BG25 is considered a GM food for Code purposes and existing labelling requirements will apply to food derived from potato line BG25 to enable informed choice as described in section 2.3.2 of this report. Further information about GM food labelling is available on the FSANZ website.[11]

[9] 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.
[10] The EPA implements and enforces the Hazardous Substances and New Organisms (HSNO) Act 1996.
[11] GM food labelling – https://www.foodstandards.gov.au/consumer/gmfood/labelling

2.2 Safety assessment

The safety assessment of potato line BG25 is provided in Supporting Document 1 (SD1) and included the following key elements:

- a characterisation of the transferred genetic material, its origin, function and stability in the potato 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 considered information from a variety of sources including, but not limited to, a data package provided by the applicant (application and study reports), the scientific literature and previous applications.

The assessment of potato line BG25 was restricted to human food safety and nutritional issues. This assessment therefore does not address any risks to the environment that may occur as the result of growing potato line BG25, or any risks to animals that may consume feed derived from potato line BG25. Permission to cultivate potato line BG25 in or to import viable tubers into Australia or New Zealand would require separate regulatory assessment and approval by the GTR in Australia and by the EPA in New Zealand.

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 potato line BG25 is considered to be as safe for human consumption as food derived from conventional non-GM potato varieties.

2.3 Risk management

Following assessment, FSANZ decided to prepare 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 either:

- 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 to correct typographical and formatting errors (see Attachment A). However, no change has been made to the risk management response proposed at the call for submissions.

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

2.3.1 Regulatory approval

Potato line BG25 is a GM food for Code purposes as it is derived from 'an organism which has been modified by gene technology'. The approved draft variation will list potato line BG25 in the table to subsection S26—3(4). This amendment will effectively provide permission for the sale and use of food derived from potato line BG25 as a GM food in accordance with the Code.

Subject to and in accordance with the draft variation, food derived from potato line BG25 may enter the Australian and New Zealand food supplies as imported food products. These may include french fries, potato flour, potato crisps or potato starch.

Cultivation of potato line BG25 Australia or New Zealand would require separate prior assessment and approval by the GTR in Australia or the EPA in New Zealand respectively.

2.3.2 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this report), food for sale derived from a GM food such as potato line BG25 will be required to be labelled as 'genetically modified' if, among other things, the GM food:

- contains novel DNA or novel protein, or
- is listed in subsection S26—3(2), (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 food derived from potato line BG25 does not have altered characteristics (see section 5.3 of SD1).

Refined products from potato line BG25, such as alcohol are unlikely to contain any novel DNA or novel protein and will be unlikely to require labelling as 'genetically modified'.

Cooked and processed products derived from potato line BG25 such as french fries, potato flour, potato crisps and potato starch will likely contain novel DNA or novel protein, and if so will require labelling as 'genetically modified'.

Should approval be granted in the future for the cultivation and/or importation of potato line BG25, the sale of raw potatoes would trigger the requirement for the 'genetically modified' statement in accordance with the labelling provisions (see section 1.3 of this report).

Section 1.5.2—4 of the Code generally requires a food for sale that consists of a genetically modified food or has a genetically modified food as an ingredient to be labelled as 'genetically modified', unless one of the exemptions listed in that section applies. Where required, 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 in the food for sale as an ingredient, food additive or processing aid, then the 'genetically modified' statement may be included in the statement of ingredients (subsection 1.5.2—4(3)).

2.3.3 Detection methodology

An Expert Advisory Group (EAG) comprising laboratory personnel and representatives of Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee[12] to identify and evaluate appropriate methods

[12] Now known as the Implementation Subcommittee for Food Regulation.

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[13]-based detection method. This sequence information was supplied by the applicant for A1289.

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 18 July 2024 and 29 August 2024. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standards News. Subscribers and interested parties were also notified.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on applications to amend the Code. 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 A1289, including the submissions received, are available on the FSANZ website[14].

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

2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ had regard to the following matters in section 29 of the FSANZ Act:

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

FSANZ has considered the costs and benefits of permitting the sale and use of food derived from a new food produced using potato line BG25, as required by the FSANZ Act. A Regulatory Impact Statement (RIS) has not been prepared for the reason stated below.

FSANZ expects that the benefits of the permission will likely exceed the costs. This assessment is discussed in more detail below.

Changes to Regulatory Impact Statement requirements

Impact analysis arrangements are no longer required to be finalised with the Office of Impact

[13] Polymerase Chain Reaction.
[14] A1289 Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25 | Food Standards Australia New Zealand

Analysis (OIA) as a result of changes made to the impact analysis requirements.[15] These changes mean FSANZ is responsible for deciding whether a RIS should be developed for proposals to amend the Code.

Prior to these changes, the OIA advised FSANZ that a RIS was not required for applications relating to GM food. This is because applications relating to permitting the use of GM food 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.

On this basis, FSANZ's assessment is that a RIS is not required for this application.

Consideration of costs and benefits under the FSANZ Act

FSANZ 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 and 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 a new GM food: potato line BG25.

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 approving the variation to the Code proposed by the application.

The benefits and costs of permitting food derived from potato line BG25

The food industry may benefit from this application being approved.

Application A1289 only relates only to the sale and use in Australia and New Zealand of food derived from potato line BG25 which is cultivated overseas. Permission to cultivate potato line BG25 in Australia or New Zealand would require separate regulatory assessment and approval by the GTR in Australia or the EPA in New Zealand respectively.

Potato line BG25 is developed to have a number of advantages that may increase productivity for growers overseas, including protection against late blight infection, protection against *Potato Virus Y* infection and reduced browning The potato line also has lower reducing sugars (fructose and glucose) which reduces the darkening of potato chips and french fries during high-temperature cooking. This may increase demand for this potato line relative to other potato varieties.

The permission is voluntary, therefore food businesses in Australia and New Zealand will only use and sell food derived from this potato line where a likely commercial net benefit exists for them.

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

The magnitude of these benefits has not been assessed.

Any benefits experienced by overseas growers may flow through to other elements of the food supply chain in Australia and New Zealand that use and sell food derived from potato line BG25, for example exporters, fresh food retailers or manufacturers of processed food.

From a regulatory impact perspective, the permission will not result in cost impacts for industry. This is because use of the permission is voluntary, businesses will only engage with foods derived from potato line BG25 where they believe a net benefit exists for them. These businesses may experience costs related to the permission, but only where they have chosen to use the permission.[16]

Consumers may benefit from greater choice in potato varieties. As noted above, potato line BG25 has lower fructose and glucose which reduces the darkening of potato chips and french fries during high-temperature cooking relative to the Russet Burbank potato variety it is based on, which some consumers may value.

There are not expected to be any significant costs to consumers, because:

- FSANZ has assessed foods derived from potato line BG25 as safe to consume
- they will have an informed choice as all food for sale that is or contains a GM food is required to be labelled in accordance with Standard 1.5.2.

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

Conclusions of consideration of costs and benefits

FSANZ 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 a new GM food: potato line BG25, 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

Cultivation in Australia or New Zealand would require independent assessment and approval by the GTR in Australia and EPA in New Zealand, respectively.

The applicant has submitted applications for regulatory approval of potato line BG25 to other countries, as listed in Table 3.

[16] For example, a processed food manufacturer may include potato derived from potato line BG25 in an existing product, replacing potato from another source. This manufacturer will be required to re-label this product to state it contains genetically modified ingredients. While updating the label is required by the Code, it is not a regulatory cost because the manufacturer did not have to use potato derived from potato line BG25.

Table 3. List of countries to whom applications for regulatory approval of BG25 have been submitted

Country	Authority	Type of approval sought	Status
United States	United States Department of Agriculture (USDA)	Determination of nonregulated status	Approved
	Environmental Protection Agency (EPA)	Environmental release	Submitted
	Food and Drug Administration (FDA)	Food and Feed	Approved
Canada	Canadian Food Inspection Agency (CFIA)	Feed and Environmental release	Submitted
	Health Canada (HC)	Food	Submitted

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 potato line BG25. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from potato line BG25 is as safe for human consumption as food derived from other conventional non-GM potato 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 potato line BG25 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

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

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2009a). Based on these principles, the risk analysis undertaken by FSANZ for potato line BG25 used the best scientific evidence available. The applicant submitted a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the applicant, other available resource material including published

scientific literature and general technical information was used by FSANZ in the safety assessment.

- **the promotion of consistency between domestic and international food standards**

There are no relevant international standards.

- **the desirability of an efficient and internationally competitive food industry**

The inclusion of GM foods in the food supply, providing there are no safety concerns, allows for innovation by developers and a widening of the technological base for producing foods. Potato line BG25 is a new food crop with resistance to the late blight fungal disease and *Potato Virus Y*, potentially enabling farmers to use less fungicide and pesticide to ensure optimal crop yields. Furthermore, the BG25 is designed to have lower reducing sugars and reduced browning in raw potatoes. The applicant has indicated that reduced browning can reduce wastage during storage and processing of potatoes, and low reducing sugars may improve storage which will potentially benefit 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 Draft variation

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

An explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

4 References

Codex (2009a) 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

Codex (2009b) Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants. CAC/GL 45-2003. Codex Alimentarius Commission, Rome. http://www.fao.org/3/a1554e/a1554e00.htm

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

FSANZ (2019) Final report – Review of food derived using new breeding techniques. https://www.foodstandards.gov.au/sites/default/files/consumer/gmfood/Documents/NBT%20Final%20report.pdf. Accessed September 2024.

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

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

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

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

Philips JG, Martin-Avila E, Robold AV (2022) Horizontal gene transfer from genetically modified plants - Regulatory considerations. Frontiers in Bioengineering and Biotechnology. 10

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

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

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 A1289 – Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of the variation.

Dated [To be completed by the delegate]

Christel Leemhuis
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1289 – Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25) 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(4) (table item 5, column headed "*Food derived from*:")

Insert:

(i) disease-resistant, low-reducing sugars and reduced browning potato line BG25

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1289 – Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25) 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 A1289 which sought to amend the Code to permit the sale and use of food derived from a new food produced using gene technology (GM food) – potato line BG25. Potato line BG25 has been genetically modified to have disease-resistance, low-reducing sugars and reduced browning. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation ─ the *Food Standards (Application A1289 – Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25) 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 draft variation.

2. Variation will be 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.[17]

This instrument is not 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

[17] See www.legislation.gov.au

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 amending the table to subsection S26—3(4) in Schedule 26 of the Code to permit the sale and use of food derived from potato line BG25, in accordance with the Code. Potato line BG25 has been genetically modified to have disease-resistance, low-reducing sugars and reduced browning.

4. Documents incorporated by reference

This 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 A1289 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 18 July 2024 for a six-week consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA).[18] 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 the use of the GM food 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

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 '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 A1289 – Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25) 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

[18] See the *Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies* | at www.pmc.gov.au.

the instrument.

Item [1] of the Schedule to the variation amends Schedule 26 by inserting, in alphabetical order, a new paragraph '(i)' into the column headed '*Food derived from:*' for item 5 of the table to subsection S26—3(4) of the Code. Item 5 of this table is headed 'Potato'.

The new paragraph (i) refers to 'disease-resistant, low-reducing sugars and reduced browning potato line BG25'.

The effect of the variation is to permit the sale and use of food derived from potato line BG25 in accordance with the Code.

Attachment C – Draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1289 – Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of the variation.

Dated [To be completed by the delegate]

Christel Leemhuis
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1289 – Food derived from disease-resistant, low-reducing sugars and reduced browning potato line BG25) 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(4) (table item 5, column headed "*Food derived from*:")

Insert:

(i) disease-resistant, low-reducing sugars and reduced browning potato line BG25