

26 May 2017
[14–17]

Call for submissions – Application A1139

Food derived from Potato Lines F10, J3, W8, X17 & Y9

FSANZ has assessed an Application made by SPS International Inc to seek approval for food derived from genetically modified (GM) potato lines W8, X17 and Y9, which have disease resistance, low acrylamide potential and reduced browning and from GM lines F10 and J3, with reduced acrylamide potential and reduced browning only. A draft food regulatory measure has been prepared. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word ‘Submission’ and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 7 July 2017

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting document

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

SD1 Safety Assessment Report

¹ <http://www.foodstandards.gov.au/code/applications/Pages/A1139PotatoE56F10J3W8X17Y9.aspx>

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from SPS International Inc to permit the sale and use of food derived from genetically modified (GM) potato lines which have reduced acrylamide potential, reduced browning (blackspot bruising) and disease resistance to foliar late blight.

For the lines assessed, 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 the potato lines are considered to be as safe for human consumption as food derived from conventional potato cultivars.

FSANZ has therefore prepared a draft variation to Schedule 26 to permit food derived from potato lines W8, X17, Y9, F10 and J3.

1 Introduction

1.1 The Applicant

SPS International Inc (SPS) 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 A1139 was lodged by SPS on 8 December 2016. It seeks approval for the sale of food derived from potatoes that have disease resistance to foliar late blight, reduced blackspot bruising and reduced acrylamide potential. Six potato lines were generated from a two-step transformation process using three common potato varieties (Russet Burbank, Ranger Russet and Atlantic).

Initially, three lines (E56, F10 and J3) were generated using an RNA interference (RNAi) approach. For the RNAi approach, four endogenous genes were targeted for suppression by inserting DNA fragments from each of the genes. The genes targeted for suppression were: asparagine synthetase-1 (*Asn1*), phosphorylase-L (*PhL*), water dikinase R1 (*R1*), and polyphenol oxidase-5 (*Ppo5*). Reducing the expression of the target genes was expected to result in a reduction in the levels of free asparagine and reducing sugars in the tuber. Asparagine and reducing sugars can react via the Maillard reaction to produce acrylamide, at temperatures consistent with frying and baking. Similarly, a reduction of polyphenols would decrease the formation of pigmented products that occur with bruising and can result in food wastage. The introduced DNA fragments are derived from the crop potato (*Solanum tuberosum* Ranger Russet) and a related species (*S. verrucosum*).

A second transformation procedure was performed on E56, F10 and J3 to create W8, X17 and Y9 respectively. An RNAi approach was used to target vacuolar invertase (*VInv*) to further decrease the levels of reducing sugars and thus the acrylamide potential of the tubers. The introduced DNA fragments were derived from the crop potato (*S. tuberosum* Ranger Russet). Additionally, a gene encoding a plant resistance protein from *S. venturii* was used to give W8, X17 and Y9 resistance to foliar late blight.

The Application initially sought approval for food derived from all six lines outlined above. However, FSANZ was unable to complete the assessment of line E56 as no compositional data was provided. For this reason, E56 is not referred to in the title of FSANZ documentation relating to the Application.

1.3 The current standard

Pre-market approval is necessary before a genetically modified (GM) food may enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment. Standard 1.5.2 – Food produced using gene technology, sets out the permission and conditions for the sale and use of food produced using gene technology (a GM food). Foods that have been assessed and approved are listed in Schedule 26.

Standard 1.5.2 also contains specific labelling provisions for approved GM foods. GM foods and ingredients must be identified on labels with the words ‘genetically modified’, if novel DNA or novel protein (as defined in Standard 1.5.2) is present in the food. Foods listed in subsections S26—3(2) and (3) of Schedule 26 must also be labelled with the words ‘genetically modified’, as well as any other additional labelling required by the Schedule, regardless of the presence of novel DNA or novel protein in the foods.

Foods listed in subsections S26—3(2) and (3) 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.

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 FSANZ Act
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Safety assessment

The safety assessment of W8, X17 and Y9, and the progenitor lines E56, F10 and J3 is provided in the supporting document (SD1). The Applicant did not provide compositional data for E56, since the line is not intended to be commercialised. FSANZ was therefore unable to complete the assessment of that line. The process of assessment included the following key elements:

- a characterisation of the transferred genetic material, its origin, function and stability in the potato genome
- the changes at the level of DNA and RNA in the whole food
- detailed compositional analyses (except E56)
- evaluation of intended and unintended changes.

The assessment of the potato lines W8, X17 and Y9 and the progenitor lines F10 and J3 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 GM plants used in food production, or any risks to animals that may consume feed derived from GM plants. Cultivation in Australia or New Zealand would require independent assessment and approval by the Office of the Gene Technology Regulator in Australia and by the Environmental Protection Authority in New Zealand (see section 2.4.1.4 below).

No potential public health and safety concerns have been identified.

Based on the data provided in the Application, and other available information, food derived from the potato lines W8, X17, Y9, F10 and J3 is considered to be as safe for human consumption as food derived from conventional potato cultivars.

2.2 Risk management

Given that food derived from W8, X17, Y9, F10 and J3 is assessed as safe as conventional potato cultivars, and that the potential benefits of permitting such food outweigh the potential costs (see analysis below), FSANZ considers that it is appropriate to permit the sale of food derived from W8, X17, Y9, F10 and J3.

2.2.1 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food derived from W8, X17, Y9, F10 and J3 would be required to be labelled as 'genetically modified' if it contains novel DNA and/or novel protein. FSANZ is not proposing to list food derived from W8, X17, Y9, F10 and J3 in subsections S26—3(2) and (3) of Schedule 26 as the compositional analyses indicate the raw agricultural product does not have an altered characteristic when compared to the existing counterpart food that is not produced using gene technology (see Section 5 of the SD1).

The raw or cooked tubers as well as processed products derived from lines W8, X17, Y9, F10 and J3 (e.g. French fries, crisps, potato starch) would be expected to contain novel DNA and/or novel protein. If so, they are likely to require labelling as 'genetically modified'. Highly processed W8, X17, Y9, F10 and J3 products such as alcohol would be unlikely to contain novel DNA or novel protein and would be unlikely to require labelling.

While one of the stated purposes of the genetic modification in W8, X17, Y9, F10 and J3 is to reduce the potential for forming acrylamide, this chemical is not a component of the raw agricultural product. It is produced only during high-temperature cooking processes, such as deep frying. The Applicant has stated that reducing acrylamide potential is desirable since acrylamide may be a health risk for consumers.

Representations made about a food derived from W8, X17, Y9, F10 and J3 (e.g. regarding the reduced acrylamide content of deep fried products) would be subject to consumer protection law in which they must be truthful and not misleading or deceptive. Additionally there are generic labelling provisions in the Food Standards Code to provide for informed consumer choice. The onus is on the supplier to determine whether any labelling requirements in the Food Standards Code would apply and are met.

2.2.2 Detection methodology

The Applicant has provided quantitative event-specific polymerase chain reaction (PCR) amplification methods for lines W8, X17, Y9, F10 and J3. As there are two transformation events, there are several detection methods available. Each method would specifically amplify DNA fragments spanning either the junction between the potato genome and the 5' regions of the T-DNA inserts or the junction between the potato genome and the 3' regions of the T-DNA inserts, for both T-DNA inserts. Since the junction sites for the inserted T-DNA is unique in each line, PCR amplification using junction specific primers can be used to detect each event unambiguously.

2.3 Risk communication

2.3.1 Consultation

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

FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release, through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

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

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Forum on Food Regulation. If the Board's decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code.

2.3.2 World Trade Organization (WTO)

Australia and New Zealand are members of the World Trade Organization (WTO) and are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with an existing or imminent international standard and that may have a significant impact on trade.

If FSANZ approves the Application to amend the Code and permit the sale of food derived from W8, X17, Y9, F10 and J3 in Australia and New Zealand, where currently sale is prohibited, there would be no significant impact on existing international standards or trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010, granted a standing exemption from the need for the OBPR to assess if a Regulatory Impact Statement is required for the approval of GM foods (ref 12065).

This standing exemption was provided as such changes are considered as minor, machinery and deregulatory in nature. The exemption relates to the introduction of a food to the food supply that has been determined to be safe.

Notwithstanding the above exemption, FSANZ conducted a cost benefit analysis. That analysis found the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the costs to the community, government or industry that would arise from the development or variation of that measure.

A consideration of the cost benefit of the regulatory options is not intended to be an exhaustive, quantitative financial analysis of the options as most of the impacts that are considered cannot be assigned a dollar value. Rather, the analysis seeks to highlight the qualitative impacts of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

The cost benefit analysis is based on W8, X17, Y9, F10 and J3 being approved for growing in other countries since the Applicant has stated that approval for cultivation in Australia or New Zealand is not currently being sought. Cultivation in Australia or New Zealand would require separate regulatory approval (see section 2.4.1.4).

Option 1 – Prepare a draft variation to Schedule 26

Consumers: Food from W8, X17, Y9, F10 and J3 has been assessed as being as safe as food from conventional cultivars of potato.

Broader availability of imported potato products since, if W8, X17, Y9, F10 and J3 are approved for commercial growing in other countries, there would be no restriction on imported foods containing these lines.

As products derived from the potato lines W8, X17, Y9, F10 and J3 are likely to contain novel DNA and/or protein, required labelling would allow consumers wishing to avoid these products to do so.

If W8, X17, Y9, F10 and J3 are approved for commercial growing in overseas countries they could be used in the manufacture of products using co-mingled potato tubers. This means that there would be no cost involved in having to exclude W8, X17, Y9, F10 and J3 from co-mingling and hence there would be no consequential need to increase the prices of imported foods that are manufactured using co-mingled potato tubers.

Government: Approval would avoid any conflict with WTO obligations. As mentioned above, food from W8, X17, Y9, F10 and J3 has been assessed as being as safe as food from conventional cultivars of potato.

This option would be cost neutral in terms of compliance costs, as monitoring is required irrespective of whether or not a GM food is approved.

In the case of approved GM foods, monitoring is required to ensure compliance with the labelling requirements, and in the case of GM foods that have not been approved, monitoring is required to ensure they are not illegally entering the food supply.

Industry: Foods derived from W8, X17, Y9, F10 and J3 would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of tubers of W8, X17, Y9, F10 and J3 from conventional tubers, as for any GM crop, will be driven by industry, based on market preferences. Implicit in this will be a due regard to the cost of segregation.

Retailers may be able to offer a broader range of potato products or imported foods manufactured using potato derivatives.

There may be additional costs to the food industry as food ingredients derived from W8, X17, Y9, F10 and J3 would require the 'genetically modified' labelling statement if they contain novel DNA and/or protein.

There may be reduced costs to farmers that could be passed onto the food industry due to a reduction in food wastage from reduced blackspot bruising. Furthermore, there could be reduced fungicide use as W8, X17 and Y9 are disease resistant.

Option 2 – Reject application

Consumers: Possible restriction in the availability of imported potato products which may be produced after co-mingling of tubers of W8, X17, Y9, F10 and J3.

No effect on consumers wishing to avoid GM foods, as food from W8, X17, Y9, F10 and J3 are not currently permitted in the food supply.

Potential increase in price of imported potato food products due to requirement for segregation of W8, X17, Y9, F10 and J3.

Government: Potential effect if considered inconsistent with WTO obligations but this would be in terms of trade policy rather than in government revenue.

Industry: Possible restriction on imports of potato food products, if W8, X17, Y9, F10 and J3 are commercialised overseas.

As food from W8, X17, Y9, F10 and J3 has been found to be as safe as food from conventional cultivars of potato, not preparing a draft variation offers little benefit to consumers, as approval of W8, X17, Y9, F10 and J3 by other countries could limit the availability of imported potato products in the Australian and New Zealand markets.

In light of the above, FSANZ considers that the potential benefits of approving the variation outweigh the potential costs.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application A1139.

2.4.1.3 Any relevant New Zealand standards

Standard 1.5.2 and Schedule 26 apply in New Zealand.

2.4.1.4 Any other relevant matters

The Applicant has submitted applications for regulatory approval of W8, X17, Y9, F10 and J3 to a number of other countries, as listed in Table 1.

The Applicant has stated they currently have no intention to apply for approval to cultivate lines W8, X17, Y9, F10 and J3 in either Australia or New Zealand.

Cultivation in Australia or New Zealand would require independent assessment and approval by the Office of the Gene Technology Regulator in Australia and by the Environmental Protection Authority in New Zealand.

Table 1: Countries currently reviewing applications for W8, X17, Y9, F10 and J3

Country	Agency		F10	J3	W8	X17	Y7
US	USDA	Environmental release & cultivation	Approved 2014	Approved 2014	Approved 2015	Approved 2016	Approved 2016
	EPA		N/A	N/A	Approved 2016	Approved 2017	Approved 2017
	FDA	Food and feed	Approved 2015	Approved 2015	Approved 2016	Approved 2017	Approved 2017
Canada	CFIA	Environmental release & feed	Approved 2016	Approved 2016	Under review	Under review	Under review
	Health Canada	Food	Approved 2016	Approved 2016	Under review	Under review	Under review

USDA: United States Department of Agriculture; EPA: US Environment Protection Agency; FDA: US Food and Drug Administration; CFIA: Canadian Food Inspection Agency.

2.4.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

Food derived from W8, X17, Y9, F10 and J3 has been assessed based on the data requirements provided in the FSANZ [Application Handbook](#)² which, in turn, reflect internationally-accepted GM food safety assessment guidelines. No public health and safety concerns were identified in this assessment. Based on the available evidence, including detailed studies provided by the Applicant, food derived from W8, X17, Y9, F10 and J3 is considered as safe and wholesome as food derived from other commercial potato cultivars.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

In accordance with existing labelling provisions to enable informed consumer choice, food derived from F10 and J3 would have to be labelled as 'genetically modified' if they contain novel DNA and food derived from W8, X17 and Y9 would have to be labelled as 'genetically modified' if they contain novel DNA and novel protein (see Section 2.2.1).

2.4.2.3 The prevention of misleading or deceptive conduct

The provision of detection methodologies by the Applicant (see Section 2.2.2) addresses this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex 2003). Based on these principles, the risk analysis undertaken for W8, X17, Y9, F10 and J3 used the best scientific evidence available. The Applicant submitted to FSANZ 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 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**

GM foods allow for innovation by developers and a widening of the technological base for producing foods. W8, X17, Y9, F10 and J3 are new food crops designed to reduce blackspot bruising in raw potatoes and acrylamide levels in cooked potato products.

²<http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

The Applicant has indicated that reduced blackspot bruising can reduce wastage during storage and processing of potatoes, and reduced acrylamide levels may provide potential health benefits to consumers. Furthermore, W8, X17 and Y9 are resistant to the fungal disease known as foliar late blight, potentially enabling farmers to use less fungicide and ensure optimal crop yields.

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

Not applicable.

- **any written policy guidelines formulated by the Forum on Food Regulation**

No specific policy guidelines have been developed.

3 Draft variation

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

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

4 References

FSANZ (2016) [Application Handbook](#)³, Part 2.3 GM applications – additional information pp.30-43. Document prepared by Food Standards Australia New Zealand.

Codex (2003) Principles for the risk analysis of foods derived from modern biotechnology. [CAC/GL 44-2003](#)⁴. Codex Alimentarius Commission, Rome.

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

³ www.foodstandards.gov.au/code/changes/Pages/applicationshandbook.aspx

⁴ www.fao.org/input/download/standards/10007/CXG_044e.pdf

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



Food Standards (Application A1139 – Food derived from Potato Lines F10, J3, W8, X17 & Y9) 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 Standards Management Officer]

Standards Management Officer
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 the above notice.

1 Name

This instrument is the *Food Standards (Application A1139 – Food derived from Potato Lines F10, J3, W8, X17 & Y9) 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

[1] Schedule 26 is varied by inserting in the table to subsection S26—3(4) in alphabetical order under item 5

- (e) reduced acrylamide potential and reduced browning potato lines F10 and J3
- (f) disease-resistant, reduced acrylamide potential and reduced browning potato lines W8, X17 and Y9

Attachment B – Draft Explanatory Statement

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.

FSANZ accepted Application A1139 which seeks approval for the sale of food derived from genetically modified potato lines W8, X17 and Y9, which are disease-resistant and have low acrylamide potential and reduced browning and from progenitor lines F10 and J3, with reduced acrylamide potential and reduced browning only. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft Standard.

2. Purpose

The Authority has prepared a draft variation that inserts a reference to reduced acrylamide potential and reduced browning potato lines F10 and J3 and disease-resistant, reduced acrylamide potential and reduced browning potato lines W8, X17 and Y9 into Schedule 26 of the Code in order to permit the sale, or use in food, of food derived from that potato line.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1139 will include one round of public consultation following an assessment and the preparation of a draft variation.

A Regulation Impact Statement was not required because the sale of food derived from W8, X17, Y9, F10 and J3, if approved, would be voluntary and would be likely to have a minor impact on business and individuals.

5. 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 94 of the FSANZ Act.

6. Variation

Item [1] inserts paragraphs (e) and (f) into item 5 of the table to subsection S26—3(4) of Schedule 26. The new paragraphs refer to reduced acrylamide potential and reduced browning potato lines F10 and J3 and disease-resistant, reduced acrylamide potential and reduced browning potato lines W8, X17 and Y9. The effect of the variation is to permit the sale and use of food derived from these potato lines in accordance with Standard 1.5.2.