

22 May 2020
[124–20]

Call for submissions – Application A1199

Food derived from Innate potato lines V11 & Z6

FSANZ has assessed an application made by SPS International Inc. seeking approval for food derived from genetically modified (GM) potato line Z6, which has disease resistance, reduced acrylamide potential and reduced browning, and from GM line V11, 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 variation.

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 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 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 three business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 09 July 2020

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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Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION.....	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION.....	3
1.3 THE CURRENT STANDARD	3
1.4 REASONS FOR ACCEPTING APPLICATION	4
1.5 PROCEDURE FOR ASSESSMENT	4
2 SUMMARY OF THE ASSESSMENT.....	4
2.1 RISK ASSESSMENT	4
2.2 RISK MANAGEMENT	5
2.2.1 <i>Labelling</i>	5
2.2.2 <i>Detection methodology</i>	6
2.3 RISK COMMUNICATION.....	6
2.3.1 <i>Consultation</i>	6
2.3.2 <i>World Trade Organization (WTO)</i>	6
2.4 FSANZ ACT ASSESSMENT REQUIREMENTS	7
2.4.1 <i>Section 29</i>	7
2.4.2 <i>Subsection 18(1)</i>	8
2.4.3 <i>Subsection 18(2) considerations</i>	9
3 DRAFT VARIATION	10
4 REFERENCES.....	10
ATTACHMENT A – DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	11
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT.....	13

Supporting document

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

SD1 Safety Assessment Report

¹ <https://www.foodstandards.gov.au/code/applications/Pages/A1199.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.

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in section 18 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), is the protection of public health and safety. Accordingly, the safety assessment is a central part of considering an application.

The safety assessment of V11 and Z6 is in Supporting Document 1. No potential public health and safety concerns have been identified. Based on the data provided and other information, food derived from V11 and Z6 is considered to be as safe for human consumption as food derived from conventional potato cultivars.

FSANZ has prepared a draft variation to Schedule 26 of the Australia New Zealand Food Standards Code (the Code) that includes a reference to food derived from potato lines V11 and Z6. The effect of the draft variation will be to permit the use or sale of food derived from these potato lines in accordance with Standard 1.5.2 of the Code.

1 Introduction

1.1 The applicant

SPS International Inc. (SPSII) 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 A1199 was lodged by SPSII on 16 December 2019. 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. Two potato lines were generated from a two-step transformation process using a common potato variety (Snowden).

Line V11 has been genetically modified to silence four endogenous genes via RNA interference (RNAi): three of the genes encode enzymes involved in the synthesis of asparagine, and the conversion of starch and sucrose into the reducing sugars, glucose and fructose. Silencing the expression of these genes reduces the levels of free asparagine and reducing sugars in the potato tuber. Asparagine and reducing sugars can react via the Maillard reaction to produce acrylamide, at temperatures consistent with frying and baking. The fourth gene that was silenced encodes an enzyme involved in the browning reaction that occurs when the potato tuber is damaged (cut or bruised). Silencing this gene reduces browning in the tuber, resulting in less food waste.

Line Z6 was derived through further genetic modification of line V11 to introduce a new gene encoding a resistance protein targeting a fungal pathogen of potato (foliar late blight) as well as silence an endogenous gene encoding an additional enzyme involved in reducing sugar formation. Line Z6 therefore shows reduced browning, further reduction in acrylamide potential (compared to V11) and is resistant to foliar late blight.

The applicant has stated that it does not currently intend to import food derived from potato lines V11 and Z6 into Australia and New Zealand, but the primary aim of its application is to protect international trade. There is a potential that food derived from potato lines V11 and Z6 may enter the Australian and New Zealand food supply as imported food products (such as french fries, potato crisps, potato flour or potato starch).

1.3 The current standard

Pre-market approval is necessary before a food produced using gene technology (GM food) can enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment. Standard 1.5.2 of the Australia New Zealand Food Standards Code (the Code) sets out the permission and conditions for the sale of food that consists of, or has as an ingredient, a food produced using gene technology. Foods that have been assessed and approved are listed in Schedule 26 of the Code.

Section 1.5.2—4 of the Code requires food to be labelled as 'genetically modified' where novel DNA and/or novel protein remains present in the final food. The requirement applies to foods for sale that consist of, or have as an ingredient (including food additives and processing aids from GM sources), food that is a GM food. Standard 1.2.1 provides that the requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer - see subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

Foods listed in subsections S26—3(2), (2A) and (3) of Schedule 26 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. Foods listed in these subsections 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.

The requirement to label food as 'genetically modified' does not apply to GM food that:

- has been highly refined (other than food that has been altered), 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, where novel DNA or novel protein from the substance does not remain present in the final food;
- is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%);
- is intended for immediate consumption and which is prepared and sold from food premises and vending machines, including restaurants, take away outlets, caterers, or self-catering institutions; or
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient.

If the GM food for sale is not required to bear a label, the labelling information in section 1.5.2—4 must accompany the food or be displayed in connection with the display of the food (in accordance with subsections 1.2.1—9(2) and (3) of Standard 1.2.1).

Subsection 1.1.1—10(8) of Standard 1.1.1 states that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

1.4 Reasons for accepting Application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the 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 Risk assessment

The safety assessment of line V11 and Z6 is provided in the supporting document (SD1). 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
- evaluation of intended and unintended changes
- the potential for any newly expressed protein to be either allergenic or toxic in humans.

The assessment of the potato lines V11 and Z6 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 (OGTR) in Australia and by the Environmental Protection Authority (EPA) in New Zealand.

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 V11 and Z6 is considered to be as safe for human consumption as food derived from conventional potato cultivars.

2.2 Risk management

2.2.1 Labelling

2.2.1.1 Requirement to be labelled as ‘genetically modified’

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food derived from potato lines V11 and Z6 would be required to be labelled as ‘genetically modified’ if it:

- contains novel DNA or novel protein; or
- is listed in section S26—3 of Schedule 26 (such food has altered characteristics).

Cooked and processed products derived from lines V11 and Z6 (e.g. French fries, potato flour, potato crisps, potato starch) would be expected to contain novel DNA and/or novel protein. If this is the case, the statement ‘genetically modified’ would need to be included on the label of the packaged food available for sale.

Should approval be granted in the future for the cultivation and/or importation of potato lines V11 and Z6, the sale of unpackaged raw potatoes (e.g. sold loose from a bulk bin) would trigger the requirement for the ‘genetically modified’ statement to accompany the food or be displayed in connection with the display of the food.

In accordance with the existing labelling provisions in Standard 1.5.2, labelling would not apply to highly processed products derived from V11 and Z6 such as alcohol, when novel DNA or novel protein is absent. The composition and characteristics of such highly refined products would be the same as those made from non-GM potato varieties.

In addition, subsection 1.5.2—4(1) would provide that the requirement to label food as ‘genetically modified’ would not apply to potato products prepared and sold for immediate consumption through restaurants, take away outlets, caterers, or self-catering institutions.

2.2.1.2 Need for additional labelling requirements

FSANZ considers whether additional labelling about the nature of any altered characteristic is required to enable consumers to make informed choices. Additional labelling (i.e. in addition to the mandatory ‘genetically modified’ statement described above) may be required if the genetic modification has significantly altered the composition or nutritional qualities of the food compared to the existing counterpart food, or if the intended use of the GM food is different to the existing counterpart food.

Given that potato lines V11 and Z6 do not have significantly altered compositional or nutritional characteristics, FSANZ has determined that no additional mandatory labelling is needed.

2.2.1.3 Voluntary representations made about food

One of the stated purposes of the genetic modification in V11 and Z6 is to reduce the potential for forming acrylamide. This chemical is not a component of the raw agricultural

product and is produced only during high-temperature cooking processes, such as deep frying. FSANZ has issued guidance² that lowering the acrylamide potential of food is important because acrylamide presents a potential health risk for consumers.

Voluntary representations made about a food derived from V11 and Z6 (e.g. regarding the reduced acrylamide content of deep fried products) would be subject to consumer protection laws, which include requirements that any representations made must be truthful and not misleading or deceptive.

2.2.2 Detection methodology

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee³ to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food produced using gene technology (GM applications).

The EAG indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the applicant for A1199.

2.3 Risk communication

2.3.1 Consultation

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

FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, media release, 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.

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

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)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to permit food derived from Innate potato lines V11 and Z6 is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations

² <https://www.foodstandards.gov.au/consumer/chemicals/acrylamide/Pages/default.aspx>

³ Now known as the Implementation Subcommittee for Food Regulation

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) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as varying Schedule 26 is a consequential change of maintaining a permitted schedule of GM foods. Additionally, permitting new GM foods is deregulatory as using the GM technology will be voluntary if the application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application). This analysis considers permitting the sale and use of food derived from GM potato lines V11 and Z6.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the sale and use of food derived from V11 and Z6. FSANZ is of the view that no other realistic food regulatory measures exist, however information received through the consultation process may result in FSANZ arriving at a different conclusion.

Costs and benefits of permitting the sale and use of food derived from V11 and Z6

The sale of foods derived from V11 and Z6 would be permitted under the Code, allowing broader market access and increased choice in raw materials. For those food products containing novel DNA or novel protein from V11 and Z6, labelling is required to assist consumers wishing to avoid these products to do so.

Due to the voluntary nature of the permission, manufacturers and retailers would only engage with foods derived from V11 and Z6, where they believe a net benefit exists for them. Part of any cost savings to industry may be passed onto consumers.

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

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting

the sale and use of food derived from GM potato lines V11 and Z6, most likely outweigh the associated 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 varying Schedule 26 as a result of Application A1199.

2.4.1.3 Any relevant New Zealand standards

Standard 1.5.2 and Schedule 26 apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.4.1.4 Any other relevant matters

The applicant has submitted applications for regulatory approval of V11 and Z6 to a number of other countries, as listed in Table 1.

The applicant has stated it currently has no intention to apply for approval to cultivate V11 and Z6 in Australia and New Zealand. Cultivation in Australia or New Zealand would require independent assessment and approval by the OGTR and NZ EPA, respectively.

Table 1: Countries currently reviewing applications for V11 and Z6

Country	Agency	Type of approval sought	V11	Z6
US	USDA	Environmental release & cultivation	Approved 2016	Under review
	EPA		N/A	Approved 2020
	FDA	Food and feed	Approved 2016	Under review
Canada	CFIA	Environmental release & feed	Approved 2016	Under review
	Health Canada	Food	Approved 2016	Under review

Further other relevant matters are considered below.

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 Innate potato lines V11 and Z6 has been assessed based on the data requirements provided in the FSANZ [Application Handbook](#)⁴ 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 V11 and Z6 is considered as safe and wholesome as food derived from other commercial potato lines.

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

Where labelling applies to food derived from Innate potato lines V11 and Z6, this would enable informed consumer choice. Consumers can seek information about food intended for immediate consumption, that is prepared and sold from a restaurant or take away outlet,

⁴ <http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

from the caterer. Information relating to foods produced using gene technology is required on labelling for food sold to a caterer (see section 2.2.1.1).

2.4.2.3 *The prevention of misleading or deceptive conduct*

The provision of detection methodology by the applicant (as described in 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, 2009). Based on these principles, the risk analysis undertaken for Innate potato lines V11 and Z6 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 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 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. Innate potato lines V11 and Z6 are new food crops designed to reduce blackspot bruising in raw potatoes and acrylamide levels in cooked potato products. 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, the Z6 line is 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**

Issues related to consumer information and safety are considered in Section 2.2 and 2.3 above.

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

No specific policy guidelines have been developed.

3 Draft variation

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

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

4 References

Codex (2009) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome. <http://www.fao.org/3/a1554e/a1554e00.htm>

Attachments

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

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



Food Standards (Application A1199 – Food derived from Innate potato lines V11 & Z6) 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]

Scott Crerar

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 A1199 – Food derived from Innate potato lines V11 & Z6) 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

- (g) reduced acrylamide potential and reduced browning potato line V11
- (h) disease-resistant, reduced acrylamide potential and reduced browning potato line Z6

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.

The Authority accepted Application A1199 which seeks approval for food derived from Innate potato lines V11 and Z6. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The purpose of the draft variation is to permit the sale of food derived from genetically modified Innate potato lines V11 and Z6.

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 A1199 will include one round of public consultation following an assessment and the preparation of a draft variation. A call for submissions (including the draft variation) will occur for a seven-week consultation period.

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 genetically modified foods (ref 12065). This standing exemption was provided as varying Schedule 26 is a consequential change of maintaining a permitted schedule of GM foods. Additionally, permitting new GM foods is deregulatory as using the GM technology will be voluntary if the application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe. As such, a Regulation Impact Statement was not required in this case as the sale of food derived from Innate potato lines V11 and Z6, 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 new paragraphs (g) and (h) into item 5 in the table to subsection S26—3(4) in Schedule 26. The new paragraphs refer to: reduced acrylamide potential and reduced browning potato line V11; and disease-resistant, reduced acrylamide potential and reduced browning potato line Z6. The effect of the variation is to permit the sale of food derived from these two potato lines in accordance with Standard 1.5.2.