

**25 September 2020**  
**[135–20]**

## **Approval report – Application A1199**

### **Food derived from Innate potato lines V11 & Z6**

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by SPS International Inc. seeking to permit the sale and use of food derived from genetically modified (GM) potato line Z6, which has disease resistance, reduced acrylamide potential and reduced browning, and from GM potato line V11, with reduced acrylamide potential and reduced browning only.

On 22 May 2020, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received eight [submissions](#) and one *Late Comment*.

FSANZ approved the draft variation on 16 September 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 24 September 2020.

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

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### Supporting document

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

SD1      Safety Assessment Report

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<sup>1</sup> <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 two genetically modified (GM) potato lines, V11 and Z6. Potato line V11 has reduced acrylamide potential and reduced browning. Potato line Z6 has disease resistance, reduced acrylamide potential and reduced browning.

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 potato lines V11 and Z6 is in Supporting Document 1 (SD1). No potential public health and safety concerns have been identified. Based on the data provided and other information, food derived from potato lines V11 and Z6 is considered to be as safe for human consumption as food derived from conventional (non-GM) potato cultivars. In addition, current labelling requirements for genetically modified food will apply to foods for sale that consist of, or have as an ingredient, food that is genetically modified.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 22 May 2020. A total of eight submissions and one *Late Comment* were received, all of which FSANZ has had regard to (see Section 2.1 of this report for a summary of submissions made and FSANZ's responses to those submissions).

FSANZ has decided to approve the draft variation proposed following assessment without change. The draft variation amends Schedule 26 of the Australia New Zealand Food Standards Code (the Code) by inserting references into that Schedule to potato lines V11 and Z6. The effect of the variation is to permit the use or sale of food derived from these potato lines in accordance with 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 and use 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.

Potato 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 silencing an endogenous gene encoding an additional enzyme involved in reducing sugar formation. Potato line Z6 therefore shows reduced browning, further reduction in acrylamide potential (compared to potato line 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 their primary aim for this application is to facilitate trade in end consumer products (such as french fries, potato crisps, potato flour or potato starch) if and when manufacturers choose to import these into Australia and New Zealand.

## 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 was assessed under the General Procedure.

## **1.6 Decision**

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

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

## 2 Summary of the assessment

### 2.1 Summary of issues raised in submissions

FSANZ called for submissions (CFS) on a proposed draft variation on 22 May 2020.

A total of eight submissions and one *Late Comment* were received, of which five were opposed to the proposed draft variation to Schedule 26. This includes a joint submission by Gene Ethics, Australian Food Sovereignty Alliance (AFSG), Pure Harvest Organic Foods, GE Free NZ, Auckland GE Free Coalition, GE Free Northland, Slow Food in Australia, FOODwatch, South Australian Genetic Food Information Network (SAGFIN), Sustainable Agriculture & Communities Alliance (SACA). AFSG and SACA, who participated in the joint submission, both provided second submissions. However, the SACA submission was received outside of the CFS timeframe and FSANZ has accepted it as a *Late Comment*.

The submitters that supported the proposed draft variation include the Victorian Department of Health and Human Services (DHHS) and the Victorian Department of Jobs, Precincts and Regions (DJPR), New Zealand Food Safety (NZFS), New Zealand Food and Groceries Council (NZFGC) and RJR Agricultural Consultants. In their submission, NZFS noted that the concentration and structure of the actual VNT1 protein in lines V11 and Z6 was not assessed, but the weight of evidence (potato phenotype, homology with proteins in the food supply, history of safe consumption, low levels of VNT1) suggest that VNT1 in potato products is unlikely to be a cause for concern. FSANZ notes the VNT1 protein has been considered by FSANZ in a previous safety assessment (A1139; FSANZ, 2017); and the applicant provided an updated bioinformatic analysis examining allergenicity and toxicity (as required by the FSANZ application handbook<sup>2</sup>). The updated information does not alter conclusions reached in the previous assessment undertaken for A1139.

Of the submissions received, many raised issues that were outside the scope of FSANZ's regulatory framework. This includes issues related to the environment, trade, country of origin labelling and general GM issues not directly related to FSANZ's food safety assessment.

Responses to safety issues raised or implied in submissions are provided in Table 1.

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<sup>2</sup> Guideline 3.5.1 B.2 (p. 105);

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

**Table 1: Summary of issues raised by submissions**

Issue	Raised by	FSANZ response
<p>Clarity regarding the origin and independence of the studies relied upon in the safety assessment; Unpublished reports were not available to the public.</p>	<p>Joint submission; AFSA; Private submitter (CB); <i>Late Comment (SACA)</i></p>	<p>In undertaking a safety assessment, FSANZ has regard to a data package from the applicant; as well as information from a variety of other sources: the scientific literature, other assessments, other government agencies, and the public.</p> <p>The data package submitted by the applicant met the FSANZ data requirements. It is a requirement that data is generated according to quality assurance guidelines that are based on internationally accepted protocols. This involves validated methodology and procedures that are consistent with Good Laboratory Practice (GLP) and can stand up to external scrutiny (i.e. independent audits and documentation trails). To achieve this, the applicant submitted a comprehensive dossier of quality-assured raw experimental data for potato lines V11 and Z6. This enabled FSANZ to independently assess the data and reach an independent conclusion about the safety of the food in question.</p> <p>The Australian Government's Information Publication Scheme and the provisions of the FSANZ Act aim to promote transparency and pro-disclosure to inform and facilitate public participation in decision-making. To this end, FSANZ places the main application and submissions on its website. For A1199, the unpublished reports provided by the applicant contained confidential information, including confidential commercial information (as defined in subsection 4(1) of the FSANZ Act) and under that Act FSANZ is not permitted to make such information publically available. Consequently, FSANZ had to redact all confidential information from those reports and only publish the redacted versions of those reports on the <a href="#">FSANZ's website</a><sup>3</sup>.</p>
<p>FSANZ's safety assessment process is deficient; The concept of substantial equivalence is not scientific.</p>	<p>Joint submission; <i>Late Comment (SACA)</i></p>	<p>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 almost 20 years ago by the Codex Alimentarius Commission (Codex 2009a, 2009b). This is a multidisciplinary approach to GM food safety assessment and uses the concept of a scientific comparison of the GM food to a non-GM counterpart having a history of safe use. This concept is also known as substantial equivalence.</p> <p>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.</p>
<p>FSANZ should consider evidence that supports the views of submitters.</p>	<p>Joint submission</p>	<p>FSANZ has regard to evidence and issues provided by submitters during the public consultation period. If such evidence raises safety issues or concerns pertinent to the specific food under assessment, FSANZ will carry out further investigation. This includes, but is not limited to, examining the scientific literature surrounding the issue and consulting with subject matter experts.</p>

<sup>3</sup> <https://www.foodstandards.gov.au/code/applications/Pages/A1199.aspx>

Issue	Raised by	FSANZ response
<p>FSANZ fails to take into account the views of Caius Rommens (former Simplot employee).</p>	<p>AFSA; Private submitter (JW)</p>	<p>In 2018, FSANZ considered the food safety concerns raised by Caius Rommens, in his book 'Pandora's Potatoes'. The concerns relate to Simplot's Innate potato brand and genetic modifications such as the reduced blackspot trait. In FSANZ's view, the concerns raised are based on very broad assumptions and FSANZ found little scientific evidence to support such claims.</p> <p>Some of the concerns raised in Pandora's Potatoes have been raised in submissions to FSANZ including concealed bruise, concealed disease, unintended effects and elevated levels of tyramine, <math>\alpha</math>-aminoadipate and chaconine-malonyl. FSANZ has addressed these issues below.</p> <p>The claims made by Caius Rommens do not change FSANZ's conclusion that food derived from potato lines V11 and Z6 is as safe for human consumption as food derived from non-GM potato cultivars.</p>
<p>Since the polyphenol oxidase (PPO) enzyme is silenced in potato lines V11 and Z6 bruising will be concealed and bruises can accumulate tyramine and other toxins; consumers will not be able to reject damaged potato products.</p>	<p>Private submitter (JW)</p>	<p>Potato tubers can exhibit different types of bruising. Blackspot is the brown discolouration that sometimes forms in bruised potatoes and is associated with PPO activity. This browning is superficial, below the skin surface and without skin breakage. The blackspot results in reduced organoleptic properties and occurs independently of signs of spoilage. The discolouration is normally removed during preparation (at home) or processing (commercially) only because it is visually unappealing in the potato, not because it is indicative of a safety concern. Unlike blackspot bruising, shatter bruising appears as damage or cracks in the skin and pressure bruising damages tissue inside the tuber and the potatoes become soft.</p> <p>Damaged potatoes generally do not reach consumers as product quality checks in the food supply chain would be able to detect and remove potatoes that contain large cracks, rotten, fermented or soft tissue due to bruising. The same processes are used for both GM and non-GM potatoes.</p> <p>Tyramine is a biogenic amine and a natural derivative of the amino acid tyrosine, one of many compounds found in the diverse phenylpropanoid family. FSANZ notes that concern about tyramine is based on the observation that phenylpropanoid levels increase under stress. However, the literature indicates that phenylpropanoid levels are quite variable in non-GM potatoes depending on the variety, location grown and environmental conditions (Payyavula et al., 2012; Reddivari et al., 2007). That is, there is a large range of natural variation of phenylpropanoids that exists in non-GM potatoes that do not raise food safety concerns.</p> <p>In terms of consumption, tyramine is present in high amounts in foods readily consumed as part of the human diet and includes cheese, cured meat and certain fish (Paulsen et al., 2012). However, compared to these foods non-GM potato tubers have very low levels of tyramine (Moret et al., 2005). Importantly, Llorente et al. (2014, 2011) have directly measured tyramine levels in three GM potato tubers with the reduced blackspot trait. The studies found that tyramine levels decreased in all tubers relative to non-GM controls.</p> <p>While tyramine consumption is not a concern for most people, some individuals can be sensitive (e.g. those using monoamine oxidase inhibitors). However, based on the evidence above, there is no credible basis to</p>



Issue	Raised by	FSANZ response
		<p>support the idea that tyramine levels in V11 and Z6 potatoes would be elevated compared to non-GM potatoes or that these potatoes pose a greater risk to sensitive individuals compared to non-GM potatoes.</p> <p>FSANZ notes that the inhibition or reduction of PPO activity to prevent browning and preserve fruits and vegetables is not a new strategy in the food industry. Many methods exist to inhibit PPO and the literature contains many examples of methods in produce such as mango, apple, pear, banana, broccoli and mushroom (Moon et al., 2020; Ioannou &amp; Ghoul, 2013). In potatoes, the food industry uses a number of preventative measures to minimise PPO activity including submerging potatoes in water or modified atmosphere packaging. Reducing PPO activity via genetic modification is but another approach to prevent browning.</p>
<p>Potato lines V11 and Z6 were not evaluated for the production of <math>\alpha</math>-aminoadipic acid that may have serious health implications; PPO silencing causes a significant increase in levels of lysine leading to increased levels of <math>\alpha</math>-aminoadipic acid.</p>	<p>Private submitter (CB)</p>	<p>The aim of the compositional analyses is to analyse only those constituents most relevant to the safety of the food or that may have an impact on the whole diet. Analysing every possible constituent in a GM food would be impractical.</p> <p>The Organisation for Economic Co-operation and development (OECD) publishes internationally recognised consensus documents on compositional considerations for various crops. These documents specify which constituents are most relevant for human health e.g. nutrients, anti-nutrients, toxicants and secondary metabolites. In potatoes, <math>\alpha</math>-aminoadipic acid, also known as <math>\alpha</math>-aminoadipate, is not considered to be a key constituent of relevance to human health.</p> <p>Plants and animals use the <math>\alpha</math>-aminoadipate pathway to catabolise lysine (Zhu et al., 2000). As shown in the SD1, the level of lysine in potato lines V11 and V6 was within the range of natural variation for non-GM potato varieties.</p> <p>Regarding specific concerns about elevated <math>\alpha</math>-aminoadipate levels in PPO-silenced potatoes, FSANZ notes that <math>\alpha</math>-aminoadipate is naturally present in a number of foods. Relative to potato, foods such as broccoli, wheat and rye contain 6.1, 7.8 and 9.5 times higher levels of <math>\alpha</math>-aminoadipate, respectively (FoodDB 2019).</p>
<p>PPO silencing causes a modest increase in the levels of chaconine-malonyl.</p>	<p>Private submitter (CB)</p>	<p>Chaconine-malonyl is a glycoalkaloid found in potato tubers and is a malonylated derivative of <math>\alpha</math>-chaconine (McCue et al., 2007). <math>\alpha</math>-chaconine, together with <math>\alpha</math>-solanine, comprise 95% of the total glycoalkaloids in potato tubers (OECD, 2015).</p> <p>Chaconine-malonyl has been shown to comprise only a very small proportion of total chaconine in potatoes (<math>\alpha</math>-chaconine + chaconine-malonyl): 1% of total chaconine in non-GM potatoes and 1.6% of total chaconine in PPO-silenced potatoes (Shepherd et al., 2015). The authors concluded the difference is relatively small and would not be a safety concern.</p> <p>FSANZ's assessment indicates the levels of glycoalkaloids in potato lines V11 and Z6 are within the range of</p>

Issue	Raised by	FSANZ response
		natural variation that exists for non-GM potatoes and do not pose a safety concern.
Since the PPO enzyme is silenced in potato lines V11 and Z6 it will conceal disease.	Private submitter (JW)	FSANZ considers that there is no evidence to support the claim that potato lines V11 and Z6 are more susceptible to disease than non-GM potatoes, or that they will not show symptoms when infected. As with non-GM tubers, V11 and Z6 tubers that exhibit disease symptoms would be removed during the usual quality checks in the food supply chain.
Concerns regarding unintended effects of genetic engineering; FSANZ should require the applicant to use 'omic' techniques to look for alterations in RNA, protein or metabolite expression.	Joint submission; AFSA; Late <i>Comment (SACA)</i>	<p>The occurrence of unintended changes is not a phenomenon specific to genetic engineering and also occurs in conventional breeding. Over the last 25 years, the accumulated evidence and regulatory experience do not support the hypothesis that GM foods have a greater propensity for unintended changes or that the technology is itself inherently harmful or a major source of risk to the consumer, compared to non-GM foods (Herman &amp; Price 2013, Ricroch 2013, Ladics et al 2015, FSANZ 2019).</p> <p>'Omics' is a generic term referring to non-targeted, profiling approaches that can measure a broad and large number of molecules. FSANZ considers that the idea that omic techniques can better inform a safety assessment is open to debate, especially since experimental conditions need to be properly controlled in order for the data to be meaningful. Several proteomic studies, for example, have repeatedly confirmed that the presence of the transgene and the genetic engineering process does not lead to unintended changes in GM crops (Gong and Wang, 2013). When differences were seen, these were associated with differences in agronomic practices, detection methodologies or disruption of endogenous genes. Further information can be found in the following papers: Cellini <i>et al</i> (2004), Chassy (2010) and Ricroch (2013).</p> <p>An analysis of the scientific shortcomings of the study cited to support the use of 'omic' techniques in safety assessments can be found in <a href="#">EFSA (2017)</a><sup>4</sup>.</p>
Strict GM labelling requirements should be imposed so that a purchaser is clearly informed; No labelling will be required.	Joint submission; AFSA, Late <i>Comment (SACA)</i> ;	<p>The labelling requirements in the Code for approved GM foods will apply. The purpose of labelling of approved GM foods is to assist consumers to make an informed choice about the food they buy. Australia's and New Zealand's GM food labelling laws are based on the presence of GM material or altered characteristics in the final food ('product-based' labelling). Food derived from potato lines V11 and Z6 will be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein, as outlined and discussed in Section 2.3.1 of this Report.</p> <p>Further information about GM food labelling can be found on the <a href="#">FSANZ website</a><sup>5</sup>.</p>
Concerns regarding the safety of	Joint submission;	The available data do not indicate the dsRNAs present in V11 and Z6 possess different characteristics, or are

<sup>4</sup> <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2017.EN-1249>

<sup>5</sup> <https://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx>

Issue	Raised by	FSANZ response
dsRNA (surviving digestion and present in circulation), RNAi and off-target unintended effects	Private submitter (JW); <i>Late Comment (SACA)</i>	<p>likely to pose a greater risk, than other RNAi mediators naturally present in potato. This includes any off-target effects. RNAi mediators, even those with homology to human genes, have a history of safe human consumption. 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 (FSANZ, 2013).</p> <p>The studies cited in the joint submission are not specific to GM crops and, in FSANZ's view, do not support the view that small RNAs in GM food are likely to have adverse consequences for humans. An analysis of the scientific shortcomings of some commonly cited studies by submitters who have concerns about small RNAs can be found on the <a href="#">FSANZ website</a><sup>6</sup>.</p>
FSANZ should require the applicant to produce a full analysis of all potential ORFs and increase the stringency of this analysis e.g. moving from 8 to 6 amino acids.	Joint submission	<p>The applicant provided an open reading frame (ORF) analysis that identified all start-to-stop ORF in both the inserted DNA and junctions between the insert and genomic DNA. The analysis is in-line with the internationally accepted guidelines of the Codex Alimentarius Commission (Codex 2009a) and did not raise any allergenicity or toxicity concerns.</p> <p>FSANZ considers that compared to the &gt;35% identity over 80 amino acid minimum requirement (Codex 2009a), there appears to be little additional value in identifying a protein's potential allergenicity using the 8 amino acid segment identity or moving from 8 to 6 amino acids. FSANZ notes peptide matches of complete identity over 6 contiguous amino acids to known allergens is associated with very poor specificity (many false positives) (WHO 2016).</p>
Potato lines V11 and Z6 are not equivalent to conventional potatoes (i.e. they are genetically modified, statistically significant amino acid difference) and therefore short and long-term feeding studies using whole potatoes are warranted; these studies should examine the safety of dsRNA and allergenicity	Joint submission; Private submitters (CB, JW); <i>Late comment (SACA)</i>	<p>While potato lines V11 and Z6 contain new DNA and traits, the compositional analysis indicates that the V11 and Z6 tubers are compositionally equivalent to tubers from non-GM varieties. Although some statistically significant differences exist between the V11 and Z6 potato lines and the non-GM comparator lines (e.g. amino acids), FSANZ considers that these are small in magnitude and not biologically relevant as the differences are within the range of natural variation that exists for potatoes.</p> <p>Most importantly, FSANZ has assessed that potato lines V11 and Z6 and non-GM potatoes are equivalent in so far as there are equally safe for human consumption. Allergenicity and the safety of dsRNA have been addressed in the SD1. FSANZ's safety assessment did not identify any new or altered hazards as a result of the genetic modification. In the absence of any new or altered hazards, additional studies such as animal or human studies of any length are unlikely to contribute any further useful information to the safety assessment and are not warranted. More information about the role of animal feeding studies can be found on the <a href="#">FSANZ website</a><sup>7</sup>.</p>

<sup>6</sup> <https://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx>

<sup>7</sup> <https://www.foodstandards.gov.au/consumer/gmfood/Pages/roleofanimalfeedings3717.aspx>

Issue	Raised by	FSANZ response
FSANZ should promote a broad-scale approach to acrylamide reduction in the whole human diet rather than approve potato lines V11 and Z6	Joint Submission	<p>GM potatoes with reduced acrylamide potential, such as potato lines V11 and Z6, are one approach for reducing acrylamide in the human diet.</p> <p>In terms of FSANZ's actions to date in relation to reducing acrylamide in the diet, FSANZ has contributed to a Codex Code of Practice document for the reduction of acrylamide in foods. FSANZ also provides advice and information to consumers about reducing their acrylamide intake on the <a href="#">FSANZ website</a><sup>8</sup>. Additional information regarding reducing acrylamide exposure in food can also be found on this <a href="#">FSANZ webpage</a><sup>9</sup>.</p>
The compositional analyses fail to disclose precisely what analytes were assessed, or the techniques used.	Joint submission	<p>The composition analysis study design and conduct for key components can be found in Section 5 of the SD1. Table 9 of the SD1 lists all the analytes measured in the potato samples. Further information on the compositional analyses can be found in the application document. Information on the specific techniques used to measure analyte levels in potato lines V11 and Z6 can be found in the appendices. These documents are publically available on the <a href="#">FSANZ website</a><sup>10</sup>.</p>
Two somewhat contradictory statements were made in the CFS document: (1) "the primary aim of this application is to protect international trade", and (2) "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".	Joint submission	<p>The two statements are not contradictory given their different context.</p> <p>Statement 1 is about consumer food products derived from two specific potatoes lines and their import into Australia and New Zealand. The applicant has indicated their intent is currently not to import food derived from potato lines V11 and Z6 directly into Australia and New Zealand, but rather to facilitate trade in end consumer products if and when manufacturers choose to import these into Australia and New Zealand. The application to permit the sale of food derived from potato lines V11 and Z6 increases the value of the raw materials to third party manufacturers that may wish to establish global supply lines.</p> <p>Statement 2 is about international trade in food per se. FSANZ does not expect that facilitating the international trade in a subset of foods derived from two specific potatoes lines will have a materially significant effect on international trade per se.</p>
Why approve unlabelled GM potatoes when there are several non-GM lines that do not pose any risk to consumers.	<i>Late comment (SACA)</i>	<p>FSANZ's thorough safety assessment concluded that potato lines V11 and Z6 are as safe and nutritious as comparable non-GM potatoes already in the Australian and New Zealand food supply. As outlined and discussed in Section 2.3.1 of this report, food derived from potato lines V11 and Z6 will be required to be labelled if it contains novel DNA or novel protein.</p>
Data on the efficacy of these potatoes in reducing acrylamide production	Joint submission	<p>The purpose of FSANZ's safety assessment of a GM food is to determine the safety of the food, not to investigate the efficacy of the particular traits in question. FSANZ notes however that data was provided on</p>

<sup>8</sup> <https://www.foodstandards.gov.au/consumer/chemicals/acrylamide/Pages/default.aspx>

<sup>9</sup> <https://www.foodstandards.gov.au/industry/Pages/Reducing-acrylamide-exposure-in-food.aspx>

<sup>10</sup> <https://www.foodstandards.gov.au/code/applications/Pages/A1199.aspx>

Issue	Raised by	FSANZ response
and blockspot are lacking.		the percentage reduction in acrylamide levels in cooked chips (Section 3.4.6.3 and Table 7 of the SD1).
The key ingredient in the applicant's product is known as "heme" or soy leghemoglobin.	ASFA	Potato lines V11 and Z6 do not contain soy leghemoglobin.
There is no assessment of the data showing significant changes to the essential amino acid profiles; The changes in concentrations of glutamine and asparagine in the GM potato lines may be of concern; Changes in the amino acid potentially affects the levels of all other compounds present in the GM potatoes.	Private submitter (CB)	<p>FSANZ assessed the levels of essential amino acids in Section 5 of the SD1.</p> <p>The levels of glutamine and asparagine in potato lines V11 and Z6 fall within the tolerance interval reported in the V11 study and combined literature range indicating these differences are within the natural variation that exists in non-GM potato.</p> <p>The compositional analysis indicates that the V11 and Z6 tubers are compositionally equivalent to tubers from non-GM varieties.</p>
The literature shows unexpected effects from ingesting GM potatoes.	Private submitter (CB)	FSANZ found no evidence in the literature pointing to adverse effects from potato lines V11 and Z6.
A study by Tacket (2007) showed that the consumption of GM potatoes causes an increase in immunoglobulin levels in humans. FSANZ is required by law to undertake a dietary exposure modelling.	Private submitter (CB)	<p>The Tacket (2007) study is not relevant to the safety of the potato lines in this application as the GM potatoes in the Tacket (2007) study were specifically and intentionally designed to trigger the immune response. Unlike the VNT1 protein expressed in potato lines V11 and Z6, the expressed proteins in Tacket (2007) are known to interact with the human immune system. FSANZ has examined the safety of the VNT1 protein and has concluded that it is unlikely to pose any safety concerns to consumers (see Section 4 of the SD1).</p> <p>As specified in the <a href="#">FSANZ Application handbook</a><sup>11</sup>, a dietary exposure assessment is carried out for GM foods that have altered nutritional characteristics. Assessing the nutritional adequacy of a GM food can, in most cases, be achieved through an understanding of the genetic modification and its consequences, together with an extensive compositional analysis. As described in Section 6 of the SD1, the introduction of food from potato lines V11 and Z6 into the food supply is expected to have little nutritional impact. As FSANZ has assessed that potato lines V11 and Z6 do not have significantly altered nutritional characteristics, a dietary exposure assessment was not carried out for the purposes of this Application.</p>
Potato lines V11 and V6 contain Timentin antibiotic resistance. Timentin will now enter the food	Private submitter	No Timentin nor any other antibiotic resistance genes are present in potato lines V11 and Z6 (Section 3.4.2 of the SD1). The antibiotic Timentin was only used during the transformation process to suppress agrobacterium growth (Section 3.1 of the SD1).

<sup>11</sup> <https://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

Issue	Raised by	FSANZ response
supply and timentin-resistant microbes will arise.	(JW)	
Transgenes can survive the process of digestion.	Late <i>Comment</i> (SACA)	In terms of risk, there is no difference between foreign DNA and the DNA already present in our diet. FSANZ has considered this issue in detail and a summary is available on the <a href="#">FSANZ website</a> <sup>12</sup> .
Concerns regarding the CRISPR/Cas9 gene editing tool.	Late <i>Comment</i> (SACA)	The genetic modification of potato lines V11 and Z6 is by agrobacterium-mediated transgenesis, not gene editing (Section 3.1 of the SD1).
FSANZ should make public the methodology used in the research laboratories.	Late <i>Comment</i> (SACA)	The genetic modification methodology is described in Section 3.1 of the SD1. The methods used to characterise the genetic modification, used in the safety assessment of novel substances and in the compositional analysis are also present in the SD1. Further information on methodologies used for potato lines V11 and Z6 can be found in the application document, as well as in the appendices. These documents are publically available on the <a href="#">FSANZ website</a> <sup>13</sup> .
FSANZ should publish information on the full analysis of the contents of the GM potatoes, so that any potential novel toxins or proteins may be identified.	Late <i>Comment</i> (SACA)	A detailed compositional analysis was performed on potato lines V11 and Z6 (see Section 5 of the SD1). Novel proteins and toxins were evaluated in Section 3.4.5 of the SD1. The characterisation and safety assessment of the VNT1 protein can be found in Section 4.1 of the SD1.
General safety concern of GM foods; a toxin from GM crops was found in human blood.	AFSA; Late <i>Comment</i> (SACA)	<p>Many concerns regarding the safety of GM foods can be traced back to a handful of studies reporting adverse effects in animals. A <a href="#">response by FSANZ</a><sup>14</sup> to some of these studies is available on our website. Further analyses of some of the other studies can be found in Snell et al (2012), Ricroch (2013) and Ricroch et al (2014).</p> <p>Before GM foods are allowed in the food supply, FSANZ conducts a thorough safety assessment. This safety assessment ensures that any approved GM foods are as safe and nutritious as comparable non-GM foods already in the Australian and New Zealand food supply. Further information can be found on the <a href="#">FSANZ webpage</a><sup>15</sup>.</p> <p>The claim linking Cry1Ab protein in blood to GM food is one that is continually circulated online. FSANZ has</p>

<sup>12</sup> <http://www.foodstandards.gov.au/consumer/gmfood/recombinantdna/Pages/default.aspx>

<sup>13</sup> <https://www.foodstandards.gov.au/code/applications/Pages/A1199.aspx>

<sup>14</sup> <http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx>

<sup>15</sup> <https://www.foodstandards.gov.au/consumer/gmfood/gmoverview/Pages/default.aspx>

Issue	Raised by	FSANZ response
		considered in detail the 2011 study which is the origin of this claim and a response is available on the <a href="#">FSANZ website</a> <sup>16</sup> .

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<sup>16</sup> <https://www.foodstandards.gov.au/consumer/gmfood/cry1ab/pages/default.aspx>

## 2.2 Safety assessment

The safety assessment of potato lines 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 safety 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 non-GM potato cultivars.

## 2.3 Risk management

### 2.3.1 Labelling

#### 2.3.1.1 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 will 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 potato lines V11 and Z6 (e.g. French fries, potato flour, potato crisps, potato starch) will 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 packaged and unpackaged raw potatoes will trigger the relevant labelling requirements in the Code.

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

In addition, consistent with paragraph 1.5.2—4(1)(e) the requirement to label food as 'genetically modified' will not apply to potato products prepared and sold for immediate consumption through restaurants, take away outlets, caterers, or self-catering institutions.



However, paragraph 1.2.1—15(f) of Standard 1.2.1 requires information relating to foods produced using gene technology to be on labelling for packaged food sold to a caterer. Subsection 1.1.2—2(3) of Standard 1.1.2 defines ‘caterer’ to mean a person, establishment or institution (for example, a catering establishment, a restaurant, a canteen, a school, or a hospital) which handles or offers food for immediate consumption. Consequently, in relation to such food, a consumer may seek information about the food from the caterer concerned.

### **2.3.1.2 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 (see, for example, subsection S26—3(3) of Schedule 26).

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.

### **2.3.1.3 Voluntary representations made about food**

One of the stated purposes of the genetic modification in potato lines 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 guidance<sup>17</sup> 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 potato lines V11 and Z6 (e.g. regarding the reduced acrylamide content of deep fried products) will be subject to consumer protection laws, which include requirements that any representations made must be truthful and not misleading or deceptive.

## **2.3.2 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-Committee<sup>18</sup> 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.

## **2.4 Risk communication**

### **2.4.1 Consultation**

Consultation is a key part of FSANZ’s standards development process. The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions are requested to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

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<sup>17</sup> <https://www.foodstandards.gov.au/consumer/chemicals/acrylamide/Pages/default.aspx>

<sup>18</sup> Now known as the Implementation Subcommittee for Food Regulation

Public submissions were invited on a draft variation which was released for public comment between 22 May 2020 and 9 July 2020. The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media tools and the publication, Food Standards News. Subscribers and interested parties were also notified.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on this Application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of the safety assessment.

Documents relating to Application A1199, including submissions received, are available on the FSANZ website.

## **2.5 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.

### **2.5.1 Section 29**

#### **2.5.1.1 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 potato lines V11 and Z6. A consideration of costs and benefits was included in the call for submissions (CFS) report based on the information and data held at that time. No further information has been received in the consultation process to date that influenced the findings from the analysis of costs and benefits in the CFS.

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 potato lines V11 and Z6.

#### *Costs and benefits of permitting the sale and use of food derived from potato lines V11 and Z6*

The sale of foods derived from potato lines 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 potato lines 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 utilise foods derived from potato lines V11 and Z6, where they believe a net benefit exists for them. Cost savings to industry may put downward pressure on prices.

Permitting food derived from potato lines V11 and Z6 may result in a small cost to government in terms of adding it to the current range of GM foods that are monitored for labelling compliance.

*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 potato lines V11 and Z6, most likely outweigh the associated costs.

**2.5.1.2 Other measures**

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than varying Schedule 26 as a result of Application A1199.

**2.5.1.3 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.

**2.5.1.4 Any other relevant matters**

The applicant has submitted applications for regulatory approval of potato lines 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 potato lines V11 and Z6 in Australia or 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.

**2.5.2 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**

Food derived from potato lines V11 and Z6 has been assessed based on the data

requirements provided in the FSANZ [Application Handbook](#)<sup>19</sup> which, in turn reflect internationally-accepted GM food safety assessment guidelines. No public health and safety concerns were identified in this safety assessment. Based on the available evidence, including detailed studies provided by the applicant, food derived from potato lines V11 and Z6 is considered as safe as food derived from other non-GM potato lines.

#### **2.5.2.2 *The provision of adequate information relating to food to enable consumers to make informed choices***

Existing labelling requirements for GM labelling will apply to food derived from Innate potato lines V11 and Z6 to enable informed consumer choice (see Section 2.3.1.1 of this Report).

#### **2.5.2.3 *The prevention of misleading or deceptive conduct***

The provision of detection methodology by the applicant (as described in Section 2.3.2 of this Report) addresses 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 Modern Biotechnology (Codex, 2009a). 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. 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 potato 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 of this Report above.

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

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<sup>19</sup> <http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

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

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## Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. 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

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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]

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 clause 3 of the variation.

**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 – 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 the sale and use of food derived from two genetically modified (GM) potato lines, V11 and Z6. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

### **2. Purpose**

The Authority has approved the draft variation amending Schedule 26 of the Code to permit the sale and use of food derived from GM potato lines V11 and Z6 in accordance with the Code.

### **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.

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 GM 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 and use of food derived from these two potato lines in accordance with the Code.