29 September 2017
[26-17]

Approval report – Application A1139

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

Food Standards Australia New Zealand (FSANZ) has assessed an Application made by SPS International Inc to seek approval for food derived from genetically modified (GM) potato lines W8, X17 and Y9, which have disease resistance, low acrylamide potential and reduced browning and from GM lines F10 and J3, with reduced acrylamide potential and reduced browning only.

On 26 May 2017, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received 58 submissions.

FSANZ approved the draft variation on 14 September 2017. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 28 September 2017.

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:

SD1 Safety Assessment Report (at Approval)[1]

[1] http://www.foodstandards.gov.au/code/applications/Pages/A1139.aspx

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from SPS International Inc on 8 December 2016. The Applicant requested a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to include food from six new genetically modified (GM) potato (*Solanum tuberosum*) lines, W8, X17, Y9, E56, F10 and J3. As the Applicant did not submit compositional data for line E56, FSANZ was unable to complete the assessment of this line, resulting in E56 being withdrawn by FSANZ from consideration.

The raw tubers of potato lines W8, X17, Y9, F10 and J3 show less browning or blackspot bruising when handled and cut, and the cooked tubers show reduced levels of acrylamide when fried. These changes have been achieved by genetic modification using an RNA interference (RNAi) approach.

Additionally, potato lines W8, X17 and Y9 show disease resistance to foliar late blight due to the introduction of novel DNA, which results in the expression of a novel protein.

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 GM potato lines W8, X17, Y9, F10 and J3 is provided in Supporting Document 1. 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 lines W8, X17, Y9, F10 and J3 is considered to be as safe for human consumption as food derived from conventional potato cultivars.

The FSANZ Board has approved the draft variation to Schedule 26 that includes a permission for food derived from reduced acrylamide potential and reduced browning potato lines F10 and J3 and disease-resistant, reduced acrylamide potential and reduced browning potato lines W8, X17 and Y9.

1 Introduction

1.1 The Applicant

Simplot Plant Sciences International Inc (SPS) is a technology provider to the agricultural sector and food industries.

1.2 The Application

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

Three lines were initially generated (E56, F10 and J3) using an RNA interference (RNAi) approach to silence genes coding for four enzymes: asparagine synthetase-1, phosphorylase-L, water dikinase R1 and polyphenol oxidase-5. This resulted in: a) lower levels of free asparagine in the tubers – asparagine can react with reducing sugars via the Maillard reaction to produce acrylamide at temperatures consistent with frying and baking; and b) a reduction of polyphenols leading to a decreased formation of pigmented products that occur with cutting and handling damage. The introduced DNA fragments are derived from the crop potato (*S. tuberosum* Ranger Russet) and a related species (*S. verrucosum*).

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

The Application initially sought approval for food derived from all six lines outlined above. However, FSANZ was unable to complete the assessment of line E56 as no compositional data was provided. For this reason, E56 was excluded from any approval consideration.

At this stage, the Applicant has indicated they have no intention to import raw tubers or cultivate these plants in Australia or New Zealand. Additional approval from the Australian Office of the Gene Technology Regulator[2] (OGTR) and the New Zealand Environmental Protection Authority[3] (NZ EPA) would be required before viable tubers could be imported into or cultivated in Australia and New Zealand. The products that are therefore likely to enter the local food market through imports would be processed foods such as par-cooked frozen potato chips, crisps, flour, starch and alcohol.

[2] http://www.ogtr.gov.au/
[3] http://www.epa.govt.nz/Pages/default.aspx

1.3 The current Standard

Pre-market approval is necessary before a GM food may enter the Australian and New Zealand food supply. Approval of such foods is contingent on completion of 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 and use of food produced using gene technology. Foods that have been assessed and approved are listed in Schedule 26.

Section 1.5.2—4 of Standard 1.5.2 also contains specific labelling provisions for approved GM foods. Packaged GM foods and ingredients (including food additives and processing aids from GM sources) must be identified on labels with the words 'genetically modified', if novel DNA or novel protein (as defined in Standard 1.5.2) is present in the food. Foods listed in subsections S26—3(2) and (3) of Schedule 26 must also be labelled with the words 'genetically modified', as well as any other additional labelling required by the Schedule, regardless of the presence of novel DNA or novel protein in the foods. Foods listed in subsections S26—3(2) and (3) are considered to have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not produced using gene technology.

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
- are substances 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 food intended for immediate consumption which is prepared and sold from food premises and vending machines, including restaurants, take away outlets, caterers, or self-catering institutions
- 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 (for example, vegetables sold loose from bulk bins), 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—Requirements to have labels or otherwise provide information).

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 gazettal. The approved draft variation is at Attachment A.

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

2.1.1 General issues raised

A total of 58 submissions were received of which 54 were opposed to the proposed draft variation to Schedule 26. Of these submissions, 40 were related to a campaign targeting Application A1139 by GE-free NZ, with related campaigns run by several other New Zealand non-government organisations (NGOs) that oppose GM food. These include GE Free Northland (1 submission), Auckland GE Free Coalition (4 submissions), Soil and Health NZ (2 submissions) and Physicians & Scientists for Global Responsibility NZ (1 submission).

Of the submissions received, many submitters raised issues that were outside the scope of FSANZ's regulatory framework. For example, issues related to social impact, environmental issues, farming practices, trade policy, and general GM issues not related to the potato lines assessed in this application.

Several submitters were concerned that importation of processed food derived from the potato lines W8, X17, Y9, F10 and J3 would allow the GM potatoes to be grown in New Zealand. This was associated with a press release from GE Free NZ[4] initiating a campaign against Application A1139, where it was claimed that approval of the Application would allow "small parts" of raw tubers to be imported into New Zealand, threatening their biosecurity. As stated in section 2.5.1.4 of this Report, if viable potatoes (i.e. those with eyes that can sprout) were to be imported into Australia and New Zealand, the Applicant would require approval from the OGTR and the NZ EPA respectively. To date, neither the OGTR nor the NZ EPA has received an application for W8, X17, Y9, F10 or J3 to be either commercially grown in Australia/New Zealand or imported into Australia/New Zealand as a viable Genetically Modified Organism. As shown in Table 2, the USA and Canada are currently the only countries to approve the cultivation of F10 and J3, with the USA approving cultivation of all lines.

Responses to general safety issues raised or implied in the opposed submissions, are provided in Table 1. Specific issues are addressed in section 2.1.2.

[4] https://livenews.co.nz/2017/06/25/make-a-submission-oppose-an-application-to-allow-ge-potatoes-in-our-food-submissions-to-food-standards-australia-nz-fsanz/

Table 1: Summary of general issues

Issue	Raised by	FSANZ response
The systems and processes used to assess and approve the application, and to monitor labelling compliance, are deeply flawed and not fit for purpose	• Auckland GE Free Coalition (AGEFC) • GE Free Northland	The approach used by FSANZ to assess the safety of GM food is based on core principles established by the Codex Alimentarius Commission (Codex 2003a; 2003b). Since 2003, the assessment protocol proposed by Codex has been subjected to scientific scrutiny and has proven to be a robust approach for whole food safety assessments. Thus it is widely adopted and implemented around the world. While philosophical opposition to the technology remains, consumers can be confident that GM foods assessed under the protocol and approved for food use are as safe as their conventional counterparts. FSANZ is not responsible for compliance with and enforcement of the Food Standards Code. In Australia, the responsibility resides with state and territory enforcement agencies, and in relation to imports, the Department of Agriculture and Water Resources. In New Zealand, the Ministry for Primary Industries in New Zealand has this responsibility.
Lack of animal feeding studies to address concerns about long term toxicity	• GE Free NZ • Joint GE Free NZ and Soil & Health Association NZ (SHNZ) • Physicians and Scientists for Global Responsibility (PSGR)	As indicated above, the approach used by FSANZ to assess the safety of GM foods is based on robust principles and guidelines that are accepted internationally and have withstood scientific scrutiny. There is general consensus among food regulators that the key focus in determining the safety of a GM food is the comparative assessment. This concept was adopted in 1993 (OECD; further information in Herman *et al,* 2009) and is applied to all GM foods. The composition and nutritional impact of food derived from the GM potatoes was considered in sections 5 and 6 of SD1. Food derived from W8, X17, Y9, F10 and J3 can be regarded as equivalent in composition to food derived from conventional potatoes and is expected to have little nutritional impact. In a workshop convened by FSANZ in 2007[5], to examine the usefulness of animal feeding studies to support the safety assessment of GM foods, the conclusion was that such studies generally do not contribute meaningful information on the long-term safety of a GM food. There were only limited circumstances where such studies may be informative, for example in the case of nutritional modification. Therefore, for most GM foods, including those derived from W8, X17, Y9, F10 and J3, feeding trials of any length are unlikely to contribute any further useful information to the safety assessment and are not warranted. There are also ethical concerns about the use of animals for feeding studies in the absence of any clearly identified compositional differences (Rigaud 2008; Bartholomaeus et al, 2013).
Insufficient evidence provided of adverse effects caused by off-target effects. FSANZ must require whole genome sequencing and molecular profiling using 'omics' techniques.	• GE Free NZ • SHNZ • AGEFC • Shirley Collins	The occurrence of unintended effects is not a phenomenon specific to recombinant DNA-mediated genetic modification and also occurs in conventional plant breeding. Extensive backcrossing is done in order to eliminate unintended effects. In both cases, those products with overt adverse phenotypic effects are easily detected and discarded during the generations that are produced prior to the selection of the line used for regulatory assessment. The compositional analyses that are an integral part of the comparative approach to safety assessment of GM foods will identify changes to key compounds, noting that such changes may not necessarily be adverse and may not fall outside the range of biological variation. Experience in assessing over 70 GM food applications by FSANZ has shown that, to date, few compounds in the GM raw agricultural commodity, from which a food is produced, fall outside biological variation unless an intended change is introduced. Non-targeted, profiling approaches are largely covered by the generic term 'omics' and, as the name implies, notionally cover all molecules of biological importance. Genomics provides information about the DNA and is approached using a number of different methods (e.g. Southern blots, polymerase chain reaction (PCR), DNA sequencing). The important feature of genomics is that the DNA is a fixed feature of an organism and therefore allows comparison over time and development.

[5] http://www.foodstandards.gov.au/consumer/gmfood/pages/roleofanimalfeedings3717.aspx

Issue	Raised by	FSANZ response
		The other –omics e.g. transcriptomics, proteomics, metabolomics and miR-omics; measure components that are subject to constant change (e.g. over time and with different agronomic practices, environment, developmental stage). To be meaningful, the data generated from these omics techniques would require comparison of the modified line, a conventional counterpart and a range of reference lines, planted at different sites and over different growing seasons, similar to the field trials performed for compositional analyses. Whether this information can better inform a safety assessment is still open to debate, especially as several proteomic studies comparing GM crops and their appropriate controls (reviewed in Gong and Wang (2013)) have shown minimal differences in the protein profiles, indicating that the presence of the transgene and the process involved in the manipulation did not lead to unintended effects in the crops examined. When differences were seen, these were associated with differences in agronomic practices, detection methodologies and disruption of endogenous genes. For other key papers discussing these issues see Cellini *et al* (2004), Chassy (2010) and Ricroch (2013).
GM crops have been shown to have adverse effects in animals	• PSGR • SHNZ • Shirley Collins • Lisa Er • Hanne Sorensen • Mary Wilson	Many respondents claimed, without citing evidence, that GM feed caused adverse effects in animal feeding studies. Other respondents cited several studies, showing a range of adverse effects. A response by FSANZ[6] to some of these studies is already 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). Given that every genetic modification event is different it is not meaningful to assume from any study on one event that the results necessarily apply to all events. As none of the studies cited were based on the GM potato lines reviewed in this Application, they were therefore not considered relevant to the safety assessment for this Application.
Unknown allergens or toxins resulting from the modification cannot be identified thus animal feeding studies required.	• PSGR • Lesley Lord • Mary Wilson	See also the response above in relation to the use of animal feeding studies for the safety assessment. The occurrence of allergies in people eating Western diets is attributed to major allergens already in the food supply – e.g. milk, eggs and nuts, particularly peanuts. These common allergenic foods are not associated with GM commodities. There is no credible scientific basis to support the notion that food allergies are linked to the introduction of any GM crops or that allergens can arise spontaneously as a result of the genetic modification process (Goodman and Tetteh, 2011). Similarly, there is no evidence that toxins can arise *de novo* as a result of the genetic modification process (Bartholomaeus *et al*, 2013). The assessment approach used for GM foods includes procedures for the assessment of potential allergenicity of any new proteins that are expressed as a result of the genetic modification. The approach relies on various criteria which together provide a weight of evidence regarding the potential allergenicity of a new protein. The criteria include the source of the protein, amino acid sequence similarity to known allergens, and resistance to digestion. If the protein is derived from a source known to be allergenic or if it is sufficiently similar to known allergens, then specific serum screening is also undertaken. Animal testing is not an option because currently no animal models are available that can reliably predict allergenicity.
GMs pose harmful health risks e.g. GM's can cause antibiotic resistance	• Mary Wilson	There are no antibiotic resistance genes expressed in the GM potato lines thus the plants are not intentionally exposed to antibiotics during their production. In the absence of selection pressure, it is highly unlikely that microorganisms associated with the potatoes during cultivation and post-harvest would develop resistance.

[6] http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx

Issue	Raised by	FSANZ response
Allowing GM crops into NZ is likely to increase consumers exposure to harmful pesticides or herbicides such as glyphosate	• Sarah Mitchell • Kate Fowler • PSGR	The approval does not allow GM potatoes to be cultivated in New Zealand. Separate approval from the NZ EPA would be required before this could occur. The GM potatoes that were assessed in this Application would be exposed to the same level and types of herbicides and insecticides as their non-GM counterparts. Furthermore, as the second generation GM varieties show resistance to foliar late blight, they would be exposed to less fungicide than their non-GM counterparts. The use of agricultural and veterinary chemicals (including any product specific excipients) is subject to strict government regulation in most trading countries. In Australia and New Zealand, residues of agricultural and veterinary chemicals are prohibited in food (both GM and non-GM) unless they comply with specific limits referred to as Maximum Residue Limits (MRLs). In New Zealand, they must comply with the MRL Food Notice for Agricultural Compounds established by the New Zealand Ministry for Primary Industries (NZ MPI). FSANZ and the Australian Pesticides and Veterinary Medicines Authority (APVMA) have shared responsibilities in relation to MRLs for food in Australia. MRLs ensure that residues of agricultural and veterinary chemicals are kept as low as possible and consistent with the approved use of chemical products to control pests and diseases of plants and animals. For further details about MRLs see the FSANZ *Chemicals in Food Factsheet*[7] and the NZ MPI website on *Pesticide Maximum Residue Limits (MRLs) for plant products*[8].
How can the statement "no biologically relevant differences" be used when no feeding studies have been performed	• SHNZ	The statement that the data shows "no biologically relevant differences" means that the measured level is consistent with that normally found in food. The fact that the level of the measured constituent may be higher or lower than the level for that constituent in the control will be of no biological relevance to humans, given the variation that already exists in our diet. Should the level of a particular constituent fall outside the range of natural variation, then further assessment may be necessary to determine if it raises a safety or nutritional concern. The type of information required to inform that assessment would have to be determined on a case-by-case basis, taking into account the nature of the constituent, and what is already known about its safety.
Current GM labelling is inadequate	• Shirley Collins • Tricia Cheel	Only those GM foods assessed by FSANZ as safe are approved for sale. The labelling of approved GM foods is therefore not for safety reasons; labelling 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) rather than 'process-based' labelling which is based solely on the production method, irrespective of the presence of GM material or altered characteristics in the final food. The current labelling laws for GM foods in Australia and New Zealand were decided by the Australia and New Zealand Food Regulation Ministerial Council (now known as The Australia and New Zealand Ministerial Forum on Food Regulation – the Forum). The Forum' s decision to base GM labelling on the final food product sought to balance the need for consumers to be provided with meaningful information, against the need for such requirements to be practical and enforceable. In December 2011, the Forum responded to recommendations contained in Labelling Logic: Review of Food Labelling Law and Policy (2011). In its response, the Forum supported the continuation of the current GM labelling provisions in the Food Standards Code and

[7] http://www.foodstandards.gov.au/ scienceandeducation/factsheets/factsheets/chemicalsinfoodmaxim5429.cfm
[8] http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm

Issue	Raised by	FSANZ response
		agreed not to pursue any additional regulatory requirements. Further information on Labelling Logic and the government response is available from the *Food Regulation*[9] website.
Food sold at food outlets do not require labelling and thus the consumer is being denied the right to know what they are eating	• GE Free NZ • AGEFC • SHNZ • Shirley Collins	Food from W8, X17, Y9, F10 and J3, if approved, would require the same labelling as any other approved GM food (see section 2.3.1 of this report). Food intended for immediate consumption that is prepared and sold from food premises and vending vehicles is exempt from GM food labelling requirements, but the consumer can seek information about the food from the food business. Information supplied by the food business must not be misleading or untruthful. The Food Standards Code requires information relating to foods produced using gene technology to be on labelling for food sold to a caterer (in the Food Standards Code, 'caterer' means 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. Section 1.3 contains further information on the labelling of GM foods.

[9] http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/Review-of-food-labelling

2.1.2 Specific issues raised

2.1.2.1 The application should not be approved as non-GM potato alternatives exist (GE Free NZ & PSGR)

No public health and safety concerns have been identified in relation to food derived from the potatoes developed by the Applicant. See section 2.2 below.

There are several varieties of potatoes that have been identified or conventionally produced to have traits like low asparagine, late blight resistance and low sugar and these will remain available for farmers and food producers to choose. The potatoes developed by the Applicant are the only lines containing all three traits in potato varieties most commonly used in the frozen chip and crisps market. Approval of these GM potatoes does not restrict the cultivation and sale of non-GM potatoes. See also section 2.5.1.1 below.

2.1.2.2 A reduction in acrylamide can be achieved by safe cooking techniques (Shirley Collins and Hanne Sorensen)

When preparing fried or high-temperature baked chips and crisps, acrylamide will be produced (Michalak et al. 2011). Acrylamide formation under these conditions is more dependent on the level of asparagine and reducing sugars in the potato than on the cooking process. Asparagine and sugar levels are determined by the variety of potato but also the way the potatoes are stored and processed post-harvest (Becalski et al. 2004; Gökmen et al. 2006; Michalak et al. 2011). Since the first report that acrylamide was found in commonly fried food products (Tareke et al. 2002) there have been many approaches taken by the agricultural, food processing and fast food industries to reduce the formation of acrylamide in chips and crisps. The potato lines W8, X17, Y9, F10 and J3 assessed in this Application make available an alternative to both farmers and the food industry to provide consumers with low acrylamide-potential food products.

2.1.2.3 Issues raised in relation to the targeted reduction of blackspot bruising (Scott Baker, Shirley Collins)

The dark colour described as a bruise or black spot and caused by polyphenol oxidase (PPO), occurs independently of signs of spoilage and 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. In other foods like prunes, cocoa beans and tea, the systemic browning caused by PPO is actually desirable (Parkin, 2008). A number of preventative measures to minimise PPO activity (and hence blackspot bruising) in potatoes are utilised in the food industry (e.g. submerging the potatoes in water, modified atmosphere packaging) and the genetic modification in F10, J3, W8, X17 and Y9 is just another approach to minimising the problem. Standard food safety protocols for potato preparation will still need to be followed for these potato lines just as for non-GM potatoes.

2.1.2.4 Application claims to contain only DNA from the Solanum genus but one must also consider the other genetic elements … such as the CaMV35S promoter, a viral promoter completely unrelated to the Solanum genus (PSGR).

There are no CaMV35S promoter sequences in either the pSIM1278 or pSIM1678 vectors used to create the potato lines W8, X17, Y9, F10 or J3.

2.1.2.5 No detail provided on how novel DNA or protein can be detected (PSGR)

The Applicant provided appropriate detection methodology for lines W8, X17, Y9, F10 and J3, as described in Section 2.3.2 of this report. Methodology for detection of protein is much less sensitive than methodology for DNA. No methodology is provided for detection of the foliar late blight resistance protein because the expression level is very low (Section 4.1.2 SD1).

2.1.2.6 The amino acid changes should not be considered inconsequential (SHNZ, GE Free NZ, Manon Guegan)

The change in asparagine and glutamine levels in the GM potato tubers was intentional and expected. The values achieved were equivalent to those found in other low-asparagine and high-glutamine non-GM potato varieties, thus it is stated that the levels fall within the range of natural variation. Furthermore, potatoes are not a major source of protein in the diet, as these potato varieties contain only about 2% protein in total. The changes that have occurred would not impact the overall dietary intake of either asparagine or glutamine, which are not considered essential amino acids.

2.1.2.7 Limited compositional analysis, including variations in anti-nutrients (GE-Free NZ)

As required by FSANZ, the Applicant submitted compositional analysis data, which did include the levels of anti-nutrients. The data provided followed the recommendations from the OECD for compositional data requirements for potatoes (OECD 2002; 2015). In particular, potatoes express a group of anti-nutrients called glycoalkaloids and this data was presented in Table 15 of SD1. The data showed no difference in glycoalkaloid levels between the parental and transformed lines.

2.1.2.8 The lack of data for F10 and J3 is inconsistent with requirements in the FSANZ Application Handbook (Vic DHHS)

An issue was raised about the lack of molecular characterisation data provided for the F10 and J3 lines. In particular, the respondent was concerned that there was no specific data related to the downregulation of the genes targeted by RNAi in these lines. FSANZ considers that the data provided for the second generation lines X17 and Y9 was sufficient for both the F10/X17 and J3/Y9 pairs, especially as there was other evidence provided for F10 and J3 to support this decision. For example, evidence was provided that showed transcription of the asparagine synthetase gene was reduced in X17, which was associated with a decrease in asparagine levels in both X17 and the progenitor line F10. This was also seen with the ineffective repression of the water dikinase gene seen in Y9, related to no change in reducing sugar levels in the progenitor line J3. The transformation step to introduce the RNAi targeting asparagine synthase and water dikinase occurred in the initial creation of F10 and J3 and the resulting traits would be expected to be consistently expressed in the secondary transformation lines. Furthermore, similar trends were seen for all the lines assessed in this application and also in the E12 line from Application A1128[10].

[10] http://www.foodstandards.gov.au/code/applications/Pages/A1128GMPotatoE12.aspx

2.2 Safety assessment

In conducting a safety assessment of food derived from W8, X17, Y9, F10 and J3, a number of criteria were addressed including:

- 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 assessment of W8, X17, Y9, F10 and J3 was restricted to human food safety and nutritional issues. This assessment therefore did 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. The Applicant has indicated that they have no intention of applying for commercial cultivation of W8, X17, Y9, F10 and J3 in Australia or New Zealand.

Some minor changes in the SD1 released with the call for submissions have been made, related to further information about the *Solanum venturii* plant and correction of minor errors.

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 W8, X17, Y9, F10 and J3 is considered to be as safe for human consumption as food derived from conventional potato varieties.

2.3 Risk management

2.3.1 Labelling

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

Cooked and processed products derived from lines W8, X17, Y9, F10 and J3 (e.g. French fries, crisps, potato starch) would be expected to contain novel DNA and/or novel protein. If 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 W8, X17, Y9, F10 and J3, 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 W8, X17, Y9, F10 and J3 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) states 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.

2.3.3.2 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 W8, X17, Y9, F10 and J3 do not have altered compositional or nutritional characteristics, FSANZ has determined that no additional mandatory labelling is needed.

2.3.3.3 Voluntary representations made about food

One of the stated purposes of the genetic modification in W8, X17, Y9, F10 and J3 was 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. The Applicant has stated that reducing acrylamide potential is desirable since acrylamide may be a health risk for consumers.

Voluntary representations made about a food derived from W8, X17, Y9, F10 and J3 (e.g. regarding the reduced acrylamide content of deep fried products) would be subject to consumer protection laws, which include requirements that any representations made must be truthful and not misleading or deceptive.

2.3.2 Detection methodology

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

2.4 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.

Public submissions were invited on a draft variation which was released for public comment between 26 May and 7 July 2017. 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 A1139, including submissions received, are available on the FSANZ website.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

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

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

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

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

The cost benefit analysis is based on W8, X17, Y9, F10 and J3 being approved for growing in other countries since the Applicant has stated that approval for cultivation in Australia or New Zealand is not currently being sought. Cultivation in Australia or New Zealand would require separate regulatory approval (see section 2.5.1.4).

Option 1 was selected.

Option 1 – Approve the draft variation to Schedule 26

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

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

Labelling of food derived from W8, X17, Y9, F10 and J3 that contains novel DNA and/or novel protein, and is sold packaged (e.g. frozen potato fries) or

unpackaged (e.g. loose potatoes sold from bulk bins), would allow consumers wishing to avoid these products to do so. Consumers are able to seek information from food premises (e.g. restaurants, takeaway outlets or caterers) that prepare food intended for immediate consumption using potato products from these lines.

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

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

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

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

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

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

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

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

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

Option 2 – reject the draft variation to Schedule 26

As food derived from potato lines W8, X17, Y9, F10 and J3 has been found to be as safe as food from conventional counterparts, not preparing a draft variation would offer little relative benefit to consumers, government and industry.

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

Standard 1.5.2 and Schedule 26 apply in New Zealand.

2.5.1.4 Any other relevant matters

The Applicant has submitted applications for regulatory approval of W8, X17, Y9, F10 and J3 to a number of other countries, as listed in Table 2.

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

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

Table 2: Countries currently reviewing applications for W8, X17, Y9, F10 and J3

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

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

Further to the information outlined in Table 2, the Y9 line will be submitted for review in Mexico, Japan, Korea, Taiwan, China, Malaysia, Philippines and Singapore.

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 W8, X17, Y9, F10 and J3 has been assessed based on the data requirements provided in the FSANZ *Application Handbook*[11] which, in turn, reflect internationally-accepted GM food safety assessment guidelines. No public health and safety concerns were identified in this assessment. Based on the available evidence, including detailed studies provided by the Applicant, food derived from W8, X17, Y9, F10 and J3 is considered as safe and wholesome as food derived from other commercial potato cultivars.

[11] http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx

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

Where labelling applies to food derived from W8, X17, Y9, F10 and J3, 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, from the caterer. Information relating to foods produced using gene technology is required on labelling for food sold to a caterer (see section 2.3.3.1).

2.5.2.3 The prevention of misleading or deceptive conduct

The provision of DNA sequence information by the Applicant will permit the detection of food derived from each of the potato lines using a PCR detection method (see section 2.3.2).

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex 2003). Based on these principles, the risk analysis undertaken for W8, X17, Y9, F10 and J3 used the best scientific evidence available. The Applicant submitted to FSANZ a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the Applicant, other available resource material including published scientific literature and general technical information was used in the safety assessment.

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

This is not a consideration as there are no relevant international standards.

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

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

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

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

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 References

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Attachments

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

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

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

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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 Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

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

1 Name

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

2 Variation to a Standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

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

(e) reduced acrylamide potential and reduced browning potato lines F10 and J3

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

Attachment B – 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 A1139 which seeks approval for food derived from genetically modified potato lines W8, X17 and Y9, which are disease-resistant and have low acrylamide potential and reduced browning. The Application also seeks approval for food derived from progenitor lines F10 and J3 which have reduced acrylamide potential and reduced browning. 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 sunsetting under the *Legislation Act 2003*.

2. Purpose

The purpose of this instrument is to amend the table to subsection S26—3(4) of Schedule 26 of the Code (permitted food produced using gene technology and conditions) to permit the use or sale of food derived from potato lines W8, X17, Y9, F10 and J3.

3. Documents incorporated by reference

This variation to a food regulatory measure does 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 A11390 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 26 May 2017 for a six-week consultation period.

A Regulation Impact Statement was not required by the Office of Best Practice Regulation (see ID 12065) because the proposed variation to Schedule 26 is likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

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