

**13 December 2016**  
**[31–16]**

## Approval Report – Application A1128

### Food derived from reduced Acrylamide Potential & Browning Potato Line E12

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by SPS International Inc seeking permission for food derived from potato line E12, the tubers of which are genetically modified to show less browning when they are bruised, cut or damaged (referred to as blackspot bruising) and to produce less acrylamide when they are cooked at high temperatures.

On 19 August 2016, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received 15 submissions.

FSANZ approved the draft variation on 6 December 2016. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 12 December 2016.

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

SD1 Safety Assessment Report (at Approval)

## Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from SPS International Inc on 25 February 2016. The Applicant requested approval for the permission of the sale and use of food derived from a genetically modified (GM) potato line which has reduced acrylamide potential and reduced browning (blackspot bruising).

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in s 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.

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<sup>1</sup> <http://www.foodstandards.gov.au/code/applications/Pages/A1128GMPotatoE12.aspx>

The safety assessment of GM potato line E12 is provided in Supporting Document 1. No potential public health and safety concerns have been identified. Based on the data provided in the present Application, and other available information, food derived from line E12 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 to include food derived from reduced acrylamide potential and reduced browning potato line E12.

# 1 Introduction

## 1.1 The Applicant

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

## 1.2 The Application

A1128 was submitted by SPS on 25 February 2016. It sought approval for food derived from a potato line with OECD Unique Identifier SPS-ØØE12-8 (herein referred to as 'E12') which has reduced acrylamide potential and reduced browning (blackspot bruise).

E12 has been genetically modified using a RNA interference (RNAi) approach. Gene fragments from four genes that were intended to suppress the expression of four endogenous potato genes were introduced into E12. The introduced gene fragments are derived from potato (*Solanum tuberosum*) and a related species (*Solanum verrucosum*). No other genetic modifications were introduced and no new proteins are produced in line E12.

The four potato genes targeted for reduced expression in the tubers were: *asparagine synthetase-1 (Asn1)*, *phosphorylase-L (PhL)*, *water dikinase R1 (R1)*, and *polyphenol oxidase-5 (Ppo5)*. The aim of suppressing *Asn1* was to reduce levels of free asparagine. The aim of suppressing *PhL* and *R1* was to reduce levels of the reducing sugars, fructose and glucose. Collectively, the reduction of free asparagine and reducing sugars was expected to result in potato tubers with reduced acrylamide potential. Reduced expression of *Ppo5* was expected to result in tubers with reduced blackspot bruising.

What actually occurred was a reduction in the expression levels of *Asn1* and *Ppo5* but not of *PhL* and *R1*. Despite not reducing the expression of *PhL* and *R1* and therefore not significantly lowering the levels of fructose and glucose, the reduction in expression of *ASn1* was sufficient by itself to produce the desired trait (reduced acrylamide production) in cooked products (fries) of E12. The reduction in *Ppo5* expression did successfully reduce the activity of polyphenol oxidase (PPO), the enzyme that leads to a darkening of damaged tissue.

## 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 (a GM food). Foods that have been assessed and approved are listed in Schedule 26.

Standard 1.5.2 also contains specific labelling provisions for approved GM foods. GM foods and ingredients (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.

## 1.4 Reasons for accepting the 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 to the Code comes into effect on gazettal. The approved draft variation to the Code 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

A total of 15 submissions were received of which 13 were opposed to the proposed draft variation to Schedule 26. Included in those opposed were four submitters, each of whom submitted the same letter (designated as 'Campaign' in Table 1 below). Also included in the 15 submissions was an on-line petition generated by an individual on [change.org](https://www.change.org/)<sup>2</sup> with 331 signatories asking FSANZ not to approve the Application. The wording of the petition did not outline any specific issues.

Several submitters were concerned that E12 could be grown in Australia or New Zealand. As stated in section 2.5.1.4 of this Report, if E12 potatoes were to be grown in Australia/New Zealand or viable E12 potatoes (i.e. those with eyes that can sprout) were to be imported into Australia or New Zealand they would require a licence/approval from the Australian Government's [Office of the Gene Technology Regulator](http://www.ogtr.gov.au/)<sup>3</sup> (OGTR) or the New Zealand Government's [Environmental Protection Authority](http://www.epa.govt.nz/Pages/default.aspx)<sup>4</sup> (NZ EPA). To date, neither the OGTR nor the NZ EPA has received an application for E12 to be either commercially grown in Australia/New Zealand or imported into Australia/New Zealand as a viable commodity. As shown in Table 2, the USA and Canada are currently the only countries to approve the cultivation of E12.

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.

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<sup>2</sup> <https://www.change.org/>

<sup>3</sup> <http://www.ogtr.gov.au/>

<sup>4</sup> <http://www.epa.govt.nz/Pages/default.aspx>

**Table 1: Summary of general issues raised in submissions**

Issue	<ul style="list-style-type: none"> <li>• Raised by</li> </ul>	FSANZ response
<p><b>Food from E12 must be labelled. Most GM potatoes imported are likely to be sold in food service outlets and require no labelling</b></p>	<ul style="list-style-type: none"> <li>• Merv Smith</li> <li>• Campaign</li> <li>• FOODWatch</li> <li>• GM-Free Australia Alliance (GMFreeAA)</li> </ul>	<p>Food from E12 potato, if approved, would require the same labelling as any other approved GM food (see section 2.3.1 of this report).</p> <p>FSANZ notes the aim of the application is to obtain food approval for imported processed foods that may contain E12. If approved, it does not preclude the importation of this GM potato for sale through food service outlets.</p> <p>The FSANZ website contains <a href="#">further information on the labelling of GM foods<sup>5</sup></a>.</p>
<p><b>Concern with the safety of all GM food and with the FSANZ approach to safety assessment</b></p>	<ul style="list-style-type: none"> <li>• Annie Davies</li> <li>• Merv Smith</li> <li>• Campaign</li> <li>• GMFreeAA</li> </ul>	<p>The approach used by FSANZ to assess the safety of GM food is based on core principles developed almost 20 years ago and published as guidelines by the Codex Alimentarius Commission (Codex 2009). Over time, the assessment protocol has been the subject of scientific scrutiny but has proved to be a robust approach for whole food safety assessments. 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.</p> <p>It is the responsibility of companies that have developed GM foods to demonstrate the safety of that food and to supply FSANZ with the raw data from scientific studies to prove this. The data must be obtained using sound scientific methods and be collected according to strict quality control criteria. This procedure is no different to that used for new chemicals and drugs as well as for any substances such as food additives, processing aids and nutritive substances (whether they are GM or not) that may be added to foods. This is standard practice for all regulatory agencies around the world. FSANZ experts review the scientific information and form their own conclusions from the results of the studies. FSANZ can, and does, request companies to undertake additional studies, where necessary. In addition, FSANZ complements the company data with information from the scientific literature, other applications and other government agencies.</p>

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

Issue	<ul style="list-style-type: none"> <li>• Raised by</li> </ul>	FSANZ response
<p><b>Feeding trials done by others indicate there are concerns to human health of using RNAi. FSANZ claims there is no need for feeding trials</b></p>	<ul style="list-style-type: none"> <li>• GMFreeAA</li> <li>• FOODWatch</li> </ul>	<p>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 compositional analysis. This concept was first considered and adopted in 1993 (OECD 1993) and there has not been any change to this approach (Herman et al. 2009).</p> <p>In 2007, FSANZ convened a workshop to formally examine the <a href="#">usefulness of animal feeding studies</a><sup>6</sup> to support the safety assessment of GM foods. The conclusion was that such studies do not contribute meaningful information on the long-term safety of a GM food, with the possible exception of a food in which the modification introduced a desired nutritional change. Therefore, for most GM foods, including those derived from E12, feeding trials of any length are unlikely to contribute any further useful information to the safety assessment and are not warranted. There are also concerns about the unethical use of animals for feeding studies in the absence of any clearly identified compositional differences (Rigaud 2008; Bartholomaeus et al. 2013).</p> <p>There is no evidence of harm to human health from ingested small RNAs and dsRNAs from either GM foods or non-GM foods. The proposal that ingested small RNAs can exert biological effects in humans is both controversial and highly speculative and has been previously discussed by FSANZ (FSANZ 2013). In relation to actual uptake, a number of conflicting pieces of evidence exist and it continues to remain an area of uncertainty. While the number of negative studies published so far suggests that uptake of ingested small RNAs does not occur to any significant extent in mammals including humans, it cannot be completely excluded. However, following uptake, there are numerous conditions that need to be met and biological barriers to be overcome before an exogenous small RNA could exert a biological effect, including a potentially adverse effect. The overwhelming evidence to date suggests this is unlikely and certainly no more likely for the small RNAs and dsRNAs produced in GM plants compared to the other small RNAs that are naturally abundant in the human diet.</p> <p>The Nunes et al (2013)<sup>7</sup> paper cited by GMFreeAA has been considered by FSANZ. While off-target effects have been observed in insects and other phyla including plants, if these effects lead to adverse phenotypic outcomes they would normally be identified early in product development. The fact that off-target effects may have occurred in an experiment undertaken in bees is of no relevance to the safety assessment of food derived from potato line E12. The extensive compositional analyses undertaken of line E12 indicate that apart from the intended changes, it is compositionally equivalent to conventional potato varieties in all other respects. The results presented in the Nunes et al paper do not alter the conclusion that ingestion of dsRNA from any source at levels normally found in food is safe in the human context. Nor do they justify a feeding trial in the case of E12.</p>

<sup>6</sup> <http://www.foodstandards.gov.au/consumer/gmfood/pages/roleofanimalfeedings3717.aspx>

<sup>7</sup> Nunes, F.M.F.; Aleixo, A.C.; Barchuk, A.R.; Bomtorin, A.D.; Grozinger, C.M.; Simoes, Z.L.P. (2013). Non-target effects of green fluorescent protein (GFP)-derived double stranded RNA (dsRNA-GFP) used in honey bee RNA interference (RNAi) assays. *Insects* 4: 90 – 103.

## 2.1.2 Specific issues raised

### 2.1.2.1 *Will the reduction in bruising of E12 mask deleterious effects in the quality of the potato that may adversely impact on safety if the potato is consumed?*

Two different consumers raised this issue in general enquiries to FSANZ, rather than as a submission and one group (GMFreeAA) raised it in a submission.

The dark colour described as a bruise or black spot and caused by 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 E12 is just another approach to minimising the problem. Standard food safety protocols for potato preparation will still need to be followed for E12 just as for non-GM potatoes.

### 2.1.2.2 *The traits in E12 can be found in other non-GM potatoes so there is no need for E12. FSANZ has neither provided evidence that acrylamide causes cancer nor investigated the efficacy of the reduced acrylamide potential of E12. There have been no studies to show E12 potatoes protect human health (GMFreeAA).*

The purpose of the assessment under Standard 1.5.2 is to consider the **safety** of a GM food. Questions of whether or not a food is needed in the food supply, or whether there is efficacy of the claimed traits expressed as a result of the genetic modification, or whether there is a health benefit of a GM food are irrelevant to a consideration of safety *per se*. None of these factors triggers a data requirement in Section 3.5.1 of the FSANZ *Application Handbook* (FSANZ 2016) which sets out safety information that must be submitted to support an application for a new GM food.

Any claims made about reduced acrylamide and cancer would be subject to other standards in the Code. Standard 1.2.7 – Nutrition, health and related claims, for example, also contains safeguards against misleading and deceptive claims. Claims that state, imply or suggest that a food or property of food has, or may have, a health effect are health claims. A health claim that refers to a serious disease (e.g. cancer) is a high level health claim and only pre-approved high level health claims in Standard 1.2.7 and Schedule S4—4 are able to be made. Currently, there are no permitted high level health claims about cancer in the Code.

In terms of acrylamide, FSANZ's position remains that, while there is no direct evidence acrylamide can cause cancer in humans, there is evidence that it can cause cancer in laboratory animals. The [24<sup>th</sup> Australian Total Diet Study](http://www.foodstandards.gov.au/publications/Pages/24th-Australian-Total-Diet-Study.aspx)<sup>8</sup> found that the exposure of Australian consumers to acrylamide is in the range considered to be of possible concern by the Joint FAO/WHO Expert Committee on Food Additives. FSANZ therefore considers it prudent for consumers to seek to reduce their exposure to acrylamide. FSANZ published a [web page on acrylamide](http://www.foodstandards.gov.au/consumer/chemicals/acrylamide/Pages/default.aspx)<sup>9</sup> and food in April 2014 stating these views. The web page includes recommendations for consumers on how to reduce acrylamide exposure, and provides links to other reputable information about acrylamide.

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<sup>8</sup> <http://www.foodstandards.gov.au/publications/Pages/24th-Australian-Total-Diet-Study.aspx>

<sup>9</sup> <http://www.foodstandards.gov.au/consumer/chemicals/acrylamide/Pages/default.aspx>

### **2.1.2.3 The Applicant has not provided the required molecular characterisation for E12 (GMFreeAA)**

As explained in the SD1 (section 3.4), the nature of the potato genome and the fact that the genetic material intended for insertion is derived from the potato genome made it impossible to accurately sequence the DNA that was inserted. However, Southern blot analyses provided a weight of evidence conclusion that the DNA had been inserted at a single site and had the same sequence arrangement as the DNA in the vector plasmid, with the exception of the loss of base pairs from the right and left border sequences. These border sequences are part of the genome of the *Agrobacterium tumefaciens* used to transform the original potato line and are commonly truncated during the transformation process (Tzfira et al. 2004; Kim et al. 2007). FSANZ experts considered all of the molecular evidence and were satisfied that the conclusion was justified.

### **2.1.2.4 In the Open Reading Frame analysis only matches with 30 or more amino acids were considered. This ignores the potential for new allergens and toxins being produced (GMFreeAA)**

As discussed in section 3.4.2 of the SD1:

- with regard to the allergenicity *in silico* analysis, “ORFs shorter than 29 amino acids were not evaluated since a minimum 35% identity requires at least a match of 29 amino acids over an 80 amino acid sequence. The 35% identity is a recommended criterion for indicating potential allergenicity (Codex 2009).”
- with regard to the toxicity *in silico* analysis, there was no minimum amino acid length for consideration of matches and therefore all matches were considered.

### **2.1.2.5 The way in which the compositional analyses for E12 were conducted is fraud not science because the control was not defined (GMFreeAA)**

As stated in section 5 of the SD1, the single control comparator for all analyses was the non-GM parental potato variety, Russet Burbank. In addition, as is standard practice, a number of commercial lines (known as reference lines) were also grown at each site and analyte levels measured in order to provide a range of values common to conventional potatoes. This range is important in allowing for an assessment of biological significance should any statistically significant differences between E12 and the control be noted for any analyte.

### **2.1.2.6 There are inconsistencies in the language in the SD1 regarding the suppression of the PhL and R1 genes and in the claims made about the lowering of levels of reducing sugars in E12 (Victorian Government Departments of Health & Human Services, and Economic Development, Jobs, Transport & Resources)**

FSANZ has altered the SD1 to address this concern. These alterations have no impact on the conclusion of the safety assessment that food derived from E12 is considered to be as safe for human consumption as food derived from conventional potato varieties. Neither is there any impact on the conclusion about the overall phenotypic traits (lower acrylamide potential and lower bruising potential) conferred on E12 as a result of the genetic modification.

### **2.1.2.7 A modification to the legal drafting for E12 is suggested (NZ MPI)**

New Zealand Ministry for Primary Industries suggested the proposed descriptor for E12 in the Column 2 entry of Schedule 26 entry (*Reduced acrylamide potential and reduced browning potato line E12*) could be modified to improve clarity.

The suggested change was *Reduced potential acrylamide formation and reduced enzymatic browning potato line E12*.

The purpose of the descriptor wording used in Schedule 26 is to provide a high level indication of the type of trait(s) that has been imparted and a precise indication of the crop and line that has been modified – the latter being the most important in terms of the permission provided by Schedule 26. FSANZ is satisfied that the descriptor used in this case is appropriate, is consistent with other permissions in Schedule 26 and is sufficiently clear.

## **2.2 Safety assessment**

The safety assessment of E12 is provided in the supporting document (SD1) and 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 assessment of E12 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. These matters are addressed by others– see section 2.5.1.4.

Inconsistencies in language describing the trait (see 2.1.2.6 above) in the SD1 released with the call for submissions have been corrected. 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 E12 is considered to be as safe for human consumption as food derived from conventional potato cultivars.

## **2.3 Risk management**

### **2.3.1 Labelling**

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this Report), food derived from E12 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 E12 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). While the level of asparagine was significantly lower than in the non-GM parent (which is widely used for frying), the level was well within the range normally found across potato varieties in general.

The genetic modification was made to reduce the expression of four endogenous potato genes; no new proteins were introduced into E12. However, the genetic modification comprised DNA from another species (*S. verrucosum*) and re-arranged segments of DNA from the same species (*S. tuberosum*) and thus is considered novel DNA. The raw or cooked E12 tuber as well as processed products derived from E12 tubers (e.g. French fries, crisps) would contain the novel DNA and are likely to require labelling as ‘genetically modified’.

Highly processed E12 products such as alcohol would be unlikely to contain novel DNA and would be unlikely to require labelling.

While one of the stated purposes of the genetic modification in E12 is to reduce the potential for forming acrylamide, this chemical is not a component of the raw agricultural product. It is produced only during high-temperature cooking processes, such as deep frying. Reducing acrylamide potential is considered to be desirable since acrylamide may be a health risk for consumers.

There are generic labelling provisions in the Code to provide for informed consumer choice. The onus is on the supplier to determine whether any labelling requirements in the Code would apply and are met, particularly as a failure to comply with these requirements can amount to an offence under Australian and New Zealand food laws. Representations made about a food derived from E12 would also be subject to other Australian and New Zealand laws designed to prevent misleading or deceptive conduct, including in relation to food.

### **2.3.2 Detection methodology**

The Applicant has provided a quantitative event-specific polymerase chain reaction (PCR) amplification method for line E12. The detection method specifically amplifies a DNA fragment spanning the junction between the potato genome and the 5' region of the T-DNA insert. Since the junction site for the inserted T-DNA is unique in E12, PCR amplification using junction specific primers can be used to detect the event unambiguously.

## **2.4 Risk communication**

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 called 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 19 August and 30 September 2016. 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 A1128, 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 genetically modified foods (ref 12065).

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

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

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

The cost/benefit analysis is based on E12 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 – Approve a draft variation to Schedule 26*

**Consumers:** Food from E12 has been assessed as being as safe as food from conventional cultivars of potato.

Broader availability of imported potato products since, if E12 is approved for commercial growing in other countries, there would be no restriction on imported foods containing this line.

For those potato line E12 products containing novel DNA (other than food sold for immediate consumption), labelling would allow consumers wishing to avoid these products to do so.

If E12 is approved for commercial growing in overseas countries, it 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 E12 from co-mingling and hence that 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 E12 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 E12 would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of tubers of E12 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 E12 would require the 'genetically modified' labelling statement if they contain novel DNA.

As food from E12 has been found to be as safe as food from conventional cultivars of potato, not preparing a draft variation would offer little benefit to consumers, as approval of E12 by other countries could limit the availability of imported potato products in the Australian and New Zealand markets.

Based on the conclusions of the safety assessments, the potential benefits of approving the variation outweighed the potential 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 a food regulatory measure developed or varied as a result of Application A1128.

#### **2.5.1.3 Any relevant New Zealand standards**

Schedule 26 applies in New Zealand.

#### **2.5.1.4 Any other relevant matters**

The Applicant has submitted applications for regulatory approval of E12 to a number of other countries, as listed in Table 2.

The Applicant has stated there is currently no intention to apply for approval to cultivate E12 in either Australia or New Zealand. There is also no intention to import live, viable potatoes (i.e. those with eyes that can sprout) for sale as fresh produce.

If E12 potatoes were to be grown in Australia/New Zealand, or viable E12 potatoes were to be imported into Australia/New Zealand, they would require a licence/approval from the Australian Government Office of the Gene Technology Regulator in Australia and by the Environmental Protection Authority in New Zealand. Australian biosecurity requirements would also have to be satisfied before importation was permitted.

Other relevant matters are considered below.

**Table 2: List of countries to whom applications for regulatory approval of E12 have been submitted**

Country	Agency	Type of approval sought	Status
USA	U.S. Department of Agriculture (USDA)	environment <sup>1</sup>	Approved 2014
	Food & Drug Administration (FDA)	food & feed	Approved 2015

Country	Agency	Type of approval sought	Status
Canada	Canadian Food Inspection Agency (CFIA)	environment & feed	Approved 2016
	Health Canada	food	Approved 2016
Japan	Ministry of Health, Labour and Welfare (MHLW)	food	Under assessment
	Ministry of Agriculture, Forestry & Fisheries (MAFF)	feed	Under assessment
Korea	Ministry of Food and Drug Safety	food & feed	Under assessment
Mexico	Department of Health (COFEPRIS)	food & feed	Preparing resubmission
China	Ministry of Agriculture	food & feed	Under assessment
Taiwan	Taiwan Food & Drug Administration	food	Under assessment

<sup>1</sup>an authorisation for 'environment' indicates the line can be grown commercially in that country.

## 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 E12 was assessed according to the safety assessment guidelines prepared by FSANZ (2007). 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 E12 is considered as safe and wholesome as food derived from other commercial potato cultivars.

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

In accordance with existing labelling provisions to enable informed consumer choice, food derived from E12 would have to be labelled as 'genetically modified' if it contains novel DNA (see section 2.3.1).

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

The requirement for detection methodology (see section 2.3.2) 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 Biotechnology (Codex 2004). Based on these principles, the risk analysis undertaken for E12 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**

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 the production of foods. E12 is a new food crop 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 that reduced acrylamide levels may provide potential health benefits to consumers.

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

Not applicable.

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

No specific policy guidelines have been developed since Standard 1.5.2 commenced.

### 3 References

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Tzfira T, Li J, Lacroix B, Cytosky V (2004) *Agrobacterium* T-DNA integration: molecules and models. *Trends in Genetics* 20(8):375–383

## 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 A1128 – Food derived from reduced Acrylamide Potential & Browning Potato Line E12) 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 A1128 – Food derived from reduced Acrylamide Potential & Browning Potato Line E12) 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

- (d) reduced acrylamide potential and reduced browning potato line E12

## **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 A1128 which seeks permission for the sale and use of food derived from a genetically modified potato line, E12, which has reduced acrylamide potential and reduced browning (blackspot bruising). 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 variation inserts a reference to reduced acrylamide potential and reduced browning line E12 into Schedule 26 in order to permit the sale, or use in food, of food derived from that potato line.

### **3. Documents incorporated by reference**

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

### **4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1128 included one round of public consultation following an assessment and the preparation of a draft variation.

A Regulation Impact Statement was not required because the sale of food derived from E12, 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 paragraph (d) into item 5 of the table to subsection S26—3(4) in Schedule 26. The new paragraph refers to reduced acrylamide potential and reduced browning potato line E12. The effect of the variation is to permit the sale and use of food derived from that potato line in accordance with Standard 1.5.2.