19 August 2016
[21–16]

Call for submissions – Application A1128

Food derived from reduced Acrylamide Potential & Browning Potato Line E12

FSANZ has assessed an Application made by SPS International Inc to seek approval for food derived from a genetically modified potato line, E12, which has reduced acrylamide potential and reduced browning (blackspot bruise). A draft food regulatory measure has been prepared. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

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

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

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

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 30 September 2016

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

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

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

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

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PO Box 10559
The Terrace WELLINGTON 6143
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Supporting documents

The following documents which informed the assessment of this Application are available on the FSANZ website at
http://www.foodstandards.gov.au/code/applications/Pages/A1128GMPotatoE12.aspx

SD1 Safety Assessment Report

Executive summary

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

This Application is being assessed under the General Procedure.

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 the 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.

FSANZ has prepared a draft variation to Schedule 26 that includes a reference to 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, USA.

1.2 The Application

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

E12 has been genetically modified using an RNA interference (RNAi) approach. Gene fragments from four genes were introduced into E12 and the expression of these fragments supresses the expression of four endogenous potato genes. The introduced DNA fragments are derived from potato (*Solanum tuberosum*) and a related species (*S. verrucosum*).

The four potato genes targeted for reduced expression are: *asparagine synthetase-1* (*Asn1*), *phosphorylase-L* (*PhL*), *water dikinase R1* (*R1*), and *polyphenol oxidase-5* (*Ppo5*). The aim of the suppression of *Asn1* is to reduce levels of free asparagine and the aim of suppression of *PhL* and *R1* is to reduce levels of the reducing sugars, fructose and glucose. Collectively, the reduction of free asparagine and reducing sugars results in potato tubers with reduced acrylamide potential when the potatoes are fried. Reduced expression of *Ppo5* results in tubers with reduced blackspot bruising. No other genetic modification has been introduced and no new proteins are produced in line E12.

1.3 The current standards

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 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 Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Safety assessment

The safety assessment of 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 potato line 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. Cultivation in Australia or New Zealand would require independent assessment and approval by the Office of the Gene Technology Regulator in Australia and by the Environmental Protection Authority in New Zealand, as the case may be (see section 2.4.1.4 below).

No potential public health and safety concerns have been identified.

Based on the data provided in the Application, and other available information, food derived from potato line E12 is considered to be as safe for human consumption as food derived from conventional potato cultivars.

2.2 Risk management

2.2.1 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this summary), 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) 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 SD1).

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, potato starch) 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.

The Applicant has stated that reducing acrylamide potential is desirable since acrylamide may be a health risk for consumers.

Representations made about a food derived from E12 (e.g. regarding the reduced acrylamide content of deep fried products of E12) would be subject to consumer protection law in which they must be truthful and not misleading or deceptive. Additionally there are generic labelling provisions in the *Australia New Zealand Food Standards Code* (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.

2.2.2 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.

2.3 Risk communication

2.3.1 Consultation

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

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

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

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

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

2.3.2 World Trade Organization (WTO)

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

There are no relevant international standards and amending the Code to permit food derived from E12 is unlikely to have a significant effect on international trade as it would permit food derived from E12 to be imported into Australia and New Zealand and sold, where currently sale is prohibited. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Cost benefit analysis

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 2.4.1.4).

Option 1 – Prepare 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, 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.

Option 2 – Reject application

Consumers: Possible restriction in the availability of imported potato products which may be produced after co-mingling of tubers of E12.

No effect on consumers wishing to avoid GM foods, as food from E12 is not currently permitted in the food supply.

Potential increase in price of imported potato food products due to requirement for segregation of E12.

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

Industry: Possible restriction on imports of potato food products, if E12 is commercialised overseas.

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

FSANZ has decided to prepare a draft variation to Schedule 26 because the potential benefits of approving the variation outweigh the potential costs, and because no public health or safety concerns resulting from consumption of food derived from E12 were identified in the safety assessment.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application A1128.

2.4.1.3 Any relevant New Zealand standards

Schedule 26 applies in New Zealand.

2.4.1.4 Any other relevant matters

The Applicant has submitted applications for regulatory approval of E12 to a number of other countries, as listed in Table 1.

The Applicant has stated they currently have no intention to apply for approval to cultivate line E12 in either Australia or New Zealand.

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

Table 1: 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[1]	Approved 2014
	Food & Drug Administration (FDA)	food & feed	Approved 2015
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	Under assessment

[1]an authorisation for 'environment' indicates the line can be grown commercially in that country.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

Food derived from E12 has been 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.

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

In accordance with existing labelling provisions to enable informed consumer choice, food derived from E12 would have to be labelled as 'genetically modified' if it contains novel DNA (see section 2.2.1).

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex 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 Draft variation

The proposed draft variation to the Code is at Attachment A and is intended to take effect on gazettal. A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

4 References

Codex (2004) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome.
http://www.codexalimentarius.net/web/standard_list.do?lang=en

FSANZ (2007) Safety assessment of genetically modified foods - guidance document. Document prepared by Food Standards Australia New Zealand.
http://www.foodstandards.gov.au/publications/Pages/Safety-Assessment-of-Genetically-Modified-Foods-Guidance-Document-.aspx

Attachments

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

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

Food Standards (Application 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 Schedule 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 – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1128 which seeks approval for food derived from a genetically modified potato line, E12, which has reduced acrylamide potential and reduced browning (blackspot bruise). The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The variation inserts a reference to reduced acrylamide potential and reduced browning line E12 into Schedule 26 of the Code in order to permit the sale, or use in food, of food derived from that potato line.

3. Documents incorporated by reference

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

4. Consultation

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

A Regulation Impact Statement was not required because the sale of food derived from 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) of 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.