FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

24 January 2012
[2-12]

APPLICATION A1064
FOOD DERIVED FROM HERBICIDE-TOLERANT SOYBEAN LINE CV127
ASSESSMENT REPORT

Executive Summary

Main points are:

- **The Application seeks approval for food derived from a genetically modified (GM), herbicide-tolerant soybean line.**
- **The Safety Assessment did not identify any potential public health and safety concerns.**
- **This Report recommends the preparation of a draft variation to the Code to include food derived from soybean line CV127 in Standard 1.5.2.**
- **At present, there is no approval to grow this GM soybean line in Australia or New Zealand. Food derived from it would therefore enter the food supply through imported products.**
- **In accordance with the labelling laws, food derived from this GM soybean line would have to be labelled as genetically modified if it contains novel DNA or novel protein.**

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from BASF Plant Science Company GmbH on 25 July 2011. The Applicant requested a variation to Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code), to permit the sale and use of food derived from genetically modified (GM) soybean line CV127, conferring herbicide-tolerance.

This Application is being assessed under the General Procedure and will include one round of public consultation.

Safety Assessment

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 forms the central component in considering an application.

A new genetically modified soybean line, CV127, is tolerant to the imidazolinone class of herbicides. Tolerance is achieved through expression of the acetohydroxyacid synthase (AHAS) catalytic subunit encoded by the *csr1-2* gene derived from the plant *Arabidopsis thaliana*.

FSANZ has completed a comprehensive safety assessment of food derived from soybean line CV127 (see **Supporting Document 1**). This assessment included consideration of (i) the genetic modification to the plant; (ii) the potential toxicity and allergenicity of the novel proteins; and (iii) the composition of food derived from soybean line CV127. No public health and safety concerns have been identified in this assessment.

On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from soybean line CV127 is considered as safe and wholesome as food derived from other commercial soybean cultivars.

Other assessment considerations

In assessing the Application, FSANZ has had regard to the following matters as prescribed in s 29 of the FSANZ Act, in addition to considering the safety of food derived from soybean line CV127:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure

- whether there are other measures that would be more cost-effective than a variation to Standard 1.5.2 and could achieve the same end

- any relevant New Zealand standards

- any other relevant matters.

Labelling

Labelling addresses the objective set out in paragraph 18(1)(b) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act); that is, the provision of adequate information relating to food to enable consumers to make informed choices. The general labelling requirements will provide consumers with information about the GM status of foods.

In accordance with general labelling provisions, food derived from soybean line CV127, if approved, would be required to be labelled as genetically modified if novel DNA or novel protein is present in the final food.

Preferred Approach

To prepare a draft variation to Standard 1.5.2 – Food produced using Gene Technology, to include food derived from herbicide-tolerant soybean line CV127 in the Schedule.

Reasons for Preferred Approach

On the basis of the available evidence, the development of a draft variation to the Code to give approval to the sale and use of food derived from herbicide-tolerant soybean line CV127 in Australia and New Zealand is proposed, for the following reasons:

- The Safety Assessment did not identify any public health and safety concerns associated with the genetic modification used to produce soybean line CV127.

- Food derived from soybean line CV127 is equivalent to that derived from the conventional soybean cultivars in terms of its safety for human consumption and nutritional adequacy.

- Labelling of food derived from soybean line CV127 will be required in the ingredients list or in conjunction with the name of the food, if it contains novel DNA or novel protein.

- Two regulatory options were considered: (1) rejection of the Application; or (2) prepare a draft variation to give approval to food derived from soybean line CV127. Following analysis of the potential costs and benefits of each option on affected parties (consumers, the food industry and government), Option 2, approval of this Application is the preferred option. Under Option 2, the potential benefits to all sectors outweigh the costs associated with the approval.

- There are no relevant New Zealand standards.

- There are no other measures that would be more cost-effective than a variation to Standard 1.5.2 and could achieve the same end.

Consultation

Public submissions are now invited on the draft variation to the Code. Comments are specifically requested on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from soybean line CV127.

As this Application is being assessed under a General Procedure, there will be one round of public comment. Responses from the public will be considered at the next stage of the assessment.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application/Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection.

If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked 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 using the Changing the Code tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 6 March 2012

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel (04) 978 5630

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SUPPORTING DOCUMENT

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1064food5241.cfm.

SD1: Safety Assessment Report: Application A1064 – Food Derived from Herbicide-Tolerant Soybean Line CV127

Introduction

On 25 July 2011, BASF Plant Science Company GmbH (BPS) submitted an Application seeking approval for food derived from soybean line CV127 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

Soybean line CV127 is tolerant to the imidazolinone class of herbicides. Tolerance is achieved through the introduction of the *csr1-2* gene, from the plant *Arabidopsis thaliana*, expressing an imidazolinone-tolerant form of the acetohydroxyacid synthase (AHAS) catalytic subunit. AHAS is involved in the biosynthesis of the branched-chain amino acids (valine, leucine, and isoleucine). The introduced AHAS catalytic subunit is able to substitute for the endogenous soybean (imidazolinone-sensitive) AHAS catalytic subunit in the presence of imidazolinone herbicides, thereby allowing the plant to remain functional. FSANZ has not previously assessed this novel protein.

The purpose of the genetic modification is to provide soybean growers with a broader weed control option.

This Assessment includes a full scientific evaluation of food derived from soybean line CV127 according to FSANZ guidelines (FSANZ, 2007) to assess its safety for human consumption. Public comment is now sought on the safety assessment and proposed recommendations prior to further consideration and completion of the Application.

1. The Issue / Problem

The Applicant has developed GM soybean line CV127. Pre-market approval is necessary before food product derived from this line may enter the Australian and New Zealand food supply. A variation to the Code granting approval to food derived from soybean line CV127 must be approved by the FSANZ Board, and that decision subsequently notified to the COAG Legislative and Governance Forum on Food Regulation[1] (FoFR). A variation to the Code may only be gazetted once this process has been finalised.

Soybean line CV127 is intended for cultivation primarily in Brazil and Argentina. Before its release into commercial markets, the Applicant is seeking regulatory approval for the line in a number of trading markets, including Australia and New Zealand. This is necessary because, once it is cultivated on a commercial-scale, processed soybean products imported into Australia and New Zealand could contain components derived from soybean line CV127. The Application is being assessed as a General Procedure.

2. Current Standard

2.1 Background

Approval of GM foods under Standard 1.5.2 is contingent upon completion of a comprehensive pre-market safety assessment. Foods that have been assessed under the Standard, if approved are listed in the Schedule to the Standard.

2.2 Overseas approvals

BPS is seeking approval for cultivation as well as food and feed use of soybean line CV127 in Brazil and Argentina. Regulatory approval for food, feed and commercial growing of CV127 in Brazil was granted by the Biosafety National Technical Commission in 2009. Regulatory approval for import, food and feed uses has also been granted in the Philippines and Mexico. Regulatory approval in Argentina is still pending.

[1] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

Submissions for regulatory approval have also been made in Canada, China, Colombia, European Union, India, Japan, Korea, Russia, South Africa, Taiwan, and the United States of America. Decisions in these countries are pending.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Questions to be answered

In completing the Assessment of this Application, the following questions were addressed:

- Based on information provided by the Applicant on the nature of the genetic modification, the molecular characterisation, the characterisation of the novel proteins, the compositional analysis and consideration of any nutritional issues, is food derived from soybean line CV127 comparable to food derived from conventional cultivars of soybean in terms of its safety for human consumption?
- Is other information available, including from the scientific literature, general technical information, independent scientists, other regulatory agencies and international bodies, and the general community, that should be taken into account in this assessment?
- Are there any other considerations that would influence the outcome of this assessment?

RISK ASSESSMENT

Food derived from soybean line CV127 has been assessed according to the safety assessment guidelines prepared by FSANZ (2007). The full Safety Assessment is provided in **Supporting Document 1**. The summary and conclusions from the Safety Assessment are presented below.

In addition to information supplied by the Applicant, other available resource material including published scientific literature and general technical information was used in this assessment.

5. Risk Assessment Summary

5.1 Safety Assessment Process

The Safety Assessment of soybean line CV127 included the following key elements: a characterisation of the transferred genes, their origin, function and stability in the soybean genome; the changes at the level of DNA, protein and in the whole food; detailed compositional analyses; evaluation of intended and unintended changes; and the potential for the newly expressed proteins to be either allergenic or toxic in humans.

The assessment of soybean line CV127 was restricted to food safety and nutritional issues. Any risks related to the release into the environment of GM plants used in food production, the safety of animal feed, or animals consuming feed derived from GM plants, or the safety of food derived from the non-GM (conventional) plant have not been addressed in this assessment.

5.2 Outcomes of the Safety Assessment

Soybean line CV127 contains a single insertion of the *csr1-2* gene expression cassette. The transformation resulted in a partial duplication of the *csr1-2* coding sequence generating a 501 bp open reading frame (ORF) that extends into the 3' flanking sequence of the inserted DNA. There is no detectable transcription of this ORF in CV127. The inserted DNA also contains the majority of the *A. thaliana SEC61γ* (*AtSEC61γ*) subunit gene, which was inadvertently included in the DNA fragment used for the transformation. This gene is weakly transcribed in CV127.

The introduced genetic elements are stably inherited from one generation to the next. No DNA sequences from the backbone of the transformation vector, including antibiotic resistance marker genes, were transferred during the transformation event.

Soybean line CV127 expresses one detectable novel protein – the AHAS catalytic subunit from *A. thaliana*. This protein is immunologically indistinguishable from the endogenous imidazolinone-sensitive soybean AHAS, therefore protein expression levels were measured as total AHAS (endogenous soybean AHAS plus *A. thaliana* AHAS). The highest AHAS levels were found in young leaves and plants but typically at levels that were too low to be quantified. The levels in soybean seed were also too low to be quantified and no AHAS protein was able to be detected in any processed soybean fraction.

The AtSEC61γ subunit protein from *A. thaliana* may also potentially be expressed in soybean line CV127, but was unable to be detected in soybean seed.

Several studies were done to confirm the identity and physicochemical and functional properties of AHAS expressed in CV127. These studies demonstrated that the AHAS protein expressed in CV127 is as expected in terms of its physicochemical and functional properties but the mature form of protein is slightly larger (by 34 amino acids) than anticipated due to the N-terminal signal peptide being cleaved at a different site to what had been previously predicted. The AHAS protein expressed in CV127 is not glycosylated and exhibits the expected enzymatic activity.

An assessment was done to determine the potential toxicity and allergenicity of the AHAS protein as well as the AtSEC61γ subunit protein (should it be expressed). Both proteins are highly homologous to proteins that have been safely consumed in food.

Bioinformatic analyses confirmed the lack of any significant amino acid sequence similarity of either protein to known protein toxins or allergens and digestibility studies demonstrated that both proteins would be rapidly digested in the gastrointestinal tract. The AHAS protein was also shown to be rapidly inactivated at temperatures > 60˚C and is not detectable in processed products such as meal, protein isolate, protein concentrate and oil. Taken together, the evidence indicates that both proteins are unlikely to be toxic or allergenic to humans.

Herbicide tolerance in soybean line CV127 is achieved by the introduction of a gene encoding a herbicide-insensitive form of the AHAS enzyme. Studies have shown that the expression of such an enzyme has no impact on the uptake, translocation and metabolism of imidazolinone herbicides by the plant. No novel metabolites would therefore be expected as a result of the genetic modification.

Detailed compositional analyses were done to establish the nutritional adequacy of seed from soybean line CV127 sprayed with imidazolinone herbicides. Analyses were done of proximate (moisture, crude protein, fat, ash, fibre), amino acid, fatty acid, vitamin, mineral, phytic acid, trypsin inhibitor, lectin, isoflavone, stachyose, raffinose and phospholipid content. The levels were compared to levels in the seeds of a control line grown alongside the GM line.

These analyses did not indicate any differences of biological significance between the seed from CV127 soybean and the control. Significant differences were noted in a number of constituents. However the differences were typically small and almost all mean values were within the range reported for conventional soybean varieties. Any observed differences therefore represent the natural variability that exists within soybean. The spraying of CV127 soybean with imidazolinone herbicides did not have a significant effect on seed composition.

In addition, no significant differences were identified in endogenous allergen content of seed from CV127 soybean compared to the non-GM counterpart.

Conclusion

No potential public health and safety concerns have been identified in the assessment of soybean line CV127. On the basis of the data provided in the present Application, and other available information, food derived from soybean line CV127 is considered to be as safe for human consumption as food derived from conventional soybean cultivars.

Risk Management

6.1 Labelling

In accordance with Division 2, Standard 1.5.2, food derived from soybean line CV127, if approved, would be required to be labelled as genetically modified if it contains novel DNA or novel protein.

Soybean CV127 is intended primarily for use as a broad-acre commodity (field soybean) to produce products derived from cracked soybeans, and is not intended for vegetable or garden purposes where food-grade products may include tofu, soybean sprouts, soy milk, and green soybean (e.g. edamame). This latter type of soybean generally has a different size, flavour and texture to field soybean. The main food product from field soybean is refined oil in which, because of the production process, novel protein and novel DNA are not likely to be present and therefore the oil is unlikely to require labelling. Other products such as protein concentrate, protein isolate and textured flour are likely to contain novel protein and/or novel DNA and if so, would require labelling.

6.2 Detection Methodology

Recently, the Implementation Sub-Committee (ISC), a sub-committee of the Food Regulation Standing Committee, agreed to the formation of an Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions, which would identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM applications. As part of its remit, the EAG will make recommendations to Australian and New Zealand enforcement agencies on suitable methods of analysis. To date this EAG has not yet been formed but, as part of an application, the Applicant is required to confirm there is a method of analysis that is fit-for-purpose.

For soybean line CV127, the Applicant has supplied a proprietary event-specific, quantitative polymerase chain reaction (PCR) detection method.

Since BPS has also submitted an application to EFSA, there is a requirement, under Regulation (EC) No 1829/2003 of the European Parliament, for an event-specific detection methodology to be supplied for assessment and validation by the European Union Reference Laboratory for GMOs in Food and Feed. Once validated, this methodology is published by the European Commission Joint Research Centre on its GMO Detection Methods database (http://gmo-crl.jrc.ec.europa.eu/gmomethods/).

7. Impact Analysis

The impact analysis represents likely impacts based on available information. The impact analysis is designed to assist in the process of identifying the affected parties, any alternative options consistent with the objective of the proposed changes, and the potential impacts of any regulatory or non-regulatory options. The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010 (reference 12065) provided an exemption from the need of the OBPR to be informed about GM food applications made to FSANZ.

There were no non-regulatory options for this Application. Two regulatory options, as follows, were considered following the assessment:

Option 1 – Reject Application

Reject the Application, thus maintaining the *status quo*.

Option 2 – Prepare a draft variation

Prepare a draft variation to Standard 1.5.2 to permit the sale and use of food derived from soybean line CV127.

7.1 Affected Parties

The affected parties may include the following:

- Consumers of soybean-containing food products, particularly those concerned about the use of biotechnology to generate new crop varieties.

- Industry sectors:

    - food importers and distributors of wholesale ingredients
    - processors and manufacturers of soybean-containing food products
    - food retailers.

- Government:

    - enforcement agencies
    - national Governments, in terms of trade and World Trade Organization (WTO) obligations.

It is the Applicant's intention that soybean line CV127 be commercially cultivated primarily in Brazil and Argentina. There is currently no intention to apply for approval to cultivate this variety in either Australia or New Zealand. Such cultivation in Australia or New Zealand could have an impact on the environment, which would need to be independently assessed by the Office of the Gene Technology Regulator (OGTR) in Australia and the Environmental Protection Authority (EPA) in New Zealand, before commercial release in either country could be permitted.

7.2 Benefit Cost Analysis

FSANZ has a statutory obligation under s 29 of the FSANZ Act to consider the cost/benefit of both options. This is not intended to be an exhaustive, quantitative dollar analysis of the options and, in fact, 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.

7.2.1 Option 1 – Reject application

Consumers: Possible restriction in the availability of imported soybean products to those products that do not contain soybean line CV127.

No impact on consumers wishing to avoid GM foods, as food from soybean line CV127 is not currently permitted in the food supply.

Potential increase in price of imported soybean foods due to requirement for segregation of soybean line CV127.

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

Industry: Possible restriction on imports of soybean food products if soybean line CV127 were to be commercialised overseas.

Potential longer-term impact - any successful WTO challenge has the potential to impact adversely on food industry.

7.2.2 Option 2 – Develop a draft regulatory measure

Consumers: Broader availability of imported soybean products as there would be no restriction on imported foods containing soybean line CV127.

Potentially, no increase in the prices of imported foods manufactured using comingled soybean products.

Appropriate labelling would allow consumers wishing to avoid certain GM soybean products to do so.

Government: Benefit that if soybean line CV127 was detected in soybean imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of soybean line CV127 would ensure no conflict with WTO responsibilities.

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. The costs of monitoring are thus expected to be comparable, whether a GM food is approved or not.

Industry: Importers of processed foods containing soybean derivatives would benefit as foods derived from soybean line CV127 would be compliant with the Code, allowing broader market access and increased choice in raw materials. Retailers may be able to offer a broader range of soybean products or imported foods manufactured using soybean derivatives.

Possible cost to food industry as some food ingredients derived from soybean line CV127 would be required to be labelled.

7.3 Comparison of Options

As food from soybean line CV127 has been found to be as safe as food from conventional cultivars of soybean, Option 1 was likely to be inconsistent with Australia's and New Zealand's WTO obligations. Option 1 would also offer little benefit to consumers, as approval of soybean line CV127 by other countries could limit the availability of imported soybean products in the Australian and New Zealand markets.

In addition, Option 1 would result in the requirement for segregation of any products containing soybean line MON87708 from those containing approved soybean lines which would be likely to increase the costs of imported soybean foods.

Based on the conclusions of the Safety Assessment, the potential benefits of Option 2 outweigh the potential costs. Preparation of a draft variation to Standard 1.5.2 giving approval to herbicide tolerant soybean line CV127 was therefore the preferred option.

Communication and Consultation Strategy

8. Communication

FSANZ has developed and will apply a basic communication strategy to this Application. The strategy involves notifying subscribers and any interested parties of the availability of the Assessment Reports for public comment and placing the reports on the FSANZ website.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the application and the impacts of regulatory options.

The issues raised in the public submissions will be evaluated and addressed in the subsequent Approval Report.

The Application for A1064 is available on the website.

The draft variation will be considered for approval by the FSANZ Board taking into consideration public comments received.

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 FoFR . If the decision to approve food derived from herbicide-tolerant soybean line CV127 is not subject to 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 FSANZ website.

9. Consultation

Public submissions are invited on the draft variation. Comments are also sought on the scientific aspects of this Application, in particular, information relevant to the safety assessment of food derived from herbicide-tolerant soybean line CV127.

9.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations 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.

The draft variation to the Code would have a trade enabling effect as it would permit food derived from herbicide-tolerant soybean line CV127 to be imported into Australia and New Zealand and sold, where currently it is prohibited. For this reason it was determined there is no need to notify this Application as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Agreement on the Application of SPS Measures.

Conclusion

10. Conclusion and Preferred Option

Preferred Approach

To prepare a draft variation to Standard 1.5.2 - Food produced using Gene Technology, to include food derived from herbicide-tolerant soybean line CV127 in the Schedule.

10.1 Reasons for Preferred Approach

The development of a variation to the Code to give approval to the sale and use of food derived from herbicide-tolerant soybean line CV127 in Australia and New Zealand is proposed on the basis of the available scientific evidence, for the following reasons:

- The Safety Assessment did not identify any public health and safety concerns associated with the genetic modification used to produce soybean line CV127.
- Food derived from soybean line CV127 is equivalent to that derived from the conventional soybean cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of food derived from soybean line CV127 will be required in the ingredients list or in conjunction with the name of the food, if it contains novel DNA or novel protein.

- Two regulatory options were considered: (1) rejection of the Application; or (2) prepare a draft variation to give approval to food derived from soybean line CV127. Following analysis of the potential costs and benefits of each option on affected parties (consumers, the food industry and government), Option 2, approval of this Application is the preferred option. Under Option 2, the potential benefits to all sectors outweigh the costs associated with the approval.

- There are no relevant New Zealand standards.

- There are no other measures that would be more cost-effective than a variation to Standard 1.5.2 and could achieve the same end.

11. Implementation

If approved, the draft variation will take effect on Gazettal.

REFERENCES

FSANZ (2007) *Safety Assessment of Genetically Modified Foods – Guidance Document*. Document prepared by Food Standards Australia New Zealand. http://www.foodstandards.gov.au/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf.

ATTACHMENTS

1. Draft Variation to the *Australia New Zealand Food Standards Code*
2. Draft Explanatory Statement

Attachment 1

Draft variation to the *Australia New Zealand Food Standards Code*

Food Standards (Application A1064 – Food derived from Herbicide-tolerant Soybean Event CV127) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated XXXX

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

1 Name

This instrument is the *Food Standards (Application A1064 – Food derived from Herbicide-tolerant Soybean Event CV127) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

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

3 Commencement

These variations commence **on the date of gazettal.**

SCHEDULE

[1] ***Standard 1.5.2*** *is varied by inserting in numerical order in the* Schedule–

	7.x	Food derived from herbicide-tolerant soybean line CV127	

Attachment 2

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 A1064 which seeks permission for the sale and use of food derived from herbicide-tolerant soybean line CV127. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to the Standard for public comment.

2. Purpose and operation

As it is not listed in the Schedule to Standard 1.5.2, food derived from soybean line CV127 is not currently permitted for sale or use in food. Therefore, FSANZ is proposing to vary Standard 1.5.2 by including food derived from soybean line CV127 in the Schedule.

3. Documents incorporated by reference

The variation 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 A1063 includes one round of public consultation following an assessment and the preparation of a draft variation. A Report (which includes the draft Standard) was released for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the use of food derived from soybean line CV127, 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

This item adds food derived from soybean line CV127 into the Schedule to Standard 1.5.2.