**25 May 2012**
**[11-12]**

# Approval Report – Application A1064

## Food derived from Herbicide-tolerant Soybean Line CV127

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by BASF Plant Science Company GmbH (BASF) seeking permission for food derived from soybean line CV127 genetically modified to provide tolerance to the imidazolinone class of herbicides.

On 24 January 2012, FSANZ sought submissions on a draft standard and published an associated report. FSANZ received 5 submissions.

FSANZ approved the draft Standard on 10 May 2012. The COAG Legislative and Governance Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 24 May 2012.

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

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

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## Supporting documents

The following documents used to prepare this Report are 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

# 1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from BASF Plant Science Company GmbH (BPS) 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, which is tolerant to the imidazolinone class of herbicides.

This Application was assessed under the General Procedure.

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 central to considering an application.

The safety assessment of soybean line CV127 is provided in SD1. No potential public health and safety concerns were identified. Based on 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.

A decision has been made to approve the draft variation to Standard 1.5.2 to include food derived from herbicide-tolerant soybean line CV127 in the Schedule.

# 2. Introduction

## 2.1 The Applicant

BASF Plant Science Company GmbH (BPS) is a technology provider to the agricultural industry.

## 2.2 The Application

Application A1064 was submitted by BPS on 25 July 2011. It sought approval for food derived from 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-insensitive 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.

## 2.3 The current Standard

Pre-market approval is necessary before food derived from any genetically modified (GM) line may enter the Australian and New Zealand food supply. Approval of GM foods under Standard 1.5.2 is contingent on 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.

Standard 1.5.2 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 and/or novel protein from an approved GM variety is present in the final food, or the food has altered characteristics. In the latter case, the Standard also allows for additional labelling about the nature of the altered characteristics.

## 2.4 Reasons for accepting the Application

The Application was accepted for assessment on the basis that:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure.

## 2.5 Procedure for assessment

The Application was assessed under the General Procedure.

## 2.6 Decision

The draft variation to Standard 1.5.2, as proposed following assessment, was approved without change.

The approved variation to the Standard is at Attachment A.

An Explanatory Statement is at Attachment B.

# 3. Summary of the findings

## 3.1 Risk assessment

The safety assessment of soybean line CV127 is provided in the supporting document (SD1) and 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 and protein in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes
- 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, or the safety of animal feed or animals consuming feed derived from GM plants have not been addressed in this assessment.

No potential public health and safety concerns have been identified.

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.

## 3.2 Risk Management

### 3.2.1 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.

### 3.2.2 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 European Food Safety Authority, 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/).

### 3.2.3 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

Public submissions were invited on a draft variation which was released for public comment between 24 January and 6 March 2012. Five submissions were received.

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

| Issue | Raised by | FSANZ Response (including any amendments to drafting) |
|---|---|---|
| **Safety of soybeans, soybean allergens** | Private individual | The issues raised concern the safety of soybeans in general, principally its allergenicity, and do not specifically relate to GM soybeans, or soybean line CV127 in particular.<br><br>It is recognised that certain foods, such as soybeans, may cause severe allergic reactions in certain individuals. For this reason, clause 4 of Standard 1.2.3 Mandatory Warning and Advisory Statements and Declarations in the Code requires soybeans and soybean products to be declared on the label when present in food as an ingredient, food additive or processing aid. For food that is exempt from bearing a label, other provisions apply for providing such information to the purchaser of the food.<br><br>These information requirements apply irrespective of whether or not the soybeans are genetically modified and irrespective of the degree of refinement or modification of the soybeans or soybean products. |

| Issue | Raised by | FSANZ Response (including any amendments to drafting) |
|---|---|---|
| **Absence of acute oral toxicity study summary from the safety assessment report (SD1)** | Food Technology Association of Australia | The submitter was primarily concerned about not having access to the details of the study.<br>A full copy of the study can be accessed on the FSANZ website at: http://www.foodstandards.gov.au/foodstandards/applications/applicationa1064food5241.cfm. |

## 3.3 Risk communication

FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was notified via the Food Standards Notification Circular and by media release and through FSANZ's social media tools and the publication *Food Standards News*. Subscribers and interested parties were also notified.

The process by which FSANZ considers standard 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.

Application A1064 is available on the website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1064food5241.cfm. Submissions are also available on the website.

# 4. Reasons for decision

The variation to the Code to permit the sale and use of food derived from herbicide-tolerant soybean line CV127 in Australia and New Zealand was approved based on available 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 counterpart and other commercially available 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.
- After analysing the potential costs and benefits, the draft variation was approved as the potential benefits to all sectors outweigh the costs associated with the approval.

## 4.1 Section 29

In reaching its decision, FSANZ had regard to the following matters under section 29 of the FSANZ Act:

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

- there were no other measures that would be more cost-effective than a variation to Standard that could achieve the same end
- any relevant New Zealand standards
- any other relevant matters.

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.

*4.1.1.1 Cost/benefit analysis*

A consideration of the cost/benefit of approving the draft variation 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.

The points below list the effect that approving the draft would be expected to have on various sectors.

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.

Based on the conclusions of the safety assessment, the potential benefits of approving the variation outweighed the potential costs.

#### *4.1.1.2 Other measures*

There were no measures that could achieve the same result other than an amendment to Standard 1.5.2.

#### *4.1.1.3 Relevant New Zealand standards*

Standard 1.5.2 applies in New Zealand.

#### *4.1.1.4 Any other relevant matters*

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 Colombia, Korea (feed only, food still pending), Mexico, Philippines, and the United States of America. Regulatory approval in Argentina is still pending. In Argentina, the regulatory assessment was concluded in November 2011 but the decision is still pending.

Submissions for regulatory approval have also been made in Canada, China, European Union, India, Japan, Russia, South Africa, and Taiwan. Decisions in these countries are pending.

## 4.2 Addressing FSANZ's objectives for standards-setting

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

### 4.2.1 Protection of public health and safety

Food derived from soybean line CV127 was assessed according to the safety assessment guidelines prepared by FSANZ (2007).

No public health and safety concerns were identified in the safety 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 commercial, conventional soybean cultivars.

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

In accordance with existing labelling provisions, food derived from soybean line CV127 will have to be labelled as 'genetically modified' if it contains novel DNA or novel protein.

### 4.2.3 The prevention of misleading or deceptive conduct

The requirement for detection methodology (see Section 3.2.2) addresses this objective.

### *4.2.4 Subsection 18(2) considerations*

FSANZ has also had regard to the objectives set out in subsection 18(2):

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

  FSANZ's approach to the safety assessment of GM foods applies scientific concepts and principles outlined in the *Codex General Principles for the Risk Analysis of Foods derived from Biotechnology* (Codex, 2004). 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*

  FSANZ assessed the safety of this GM food in accordance with internationally established scientific principles and guidelines developed through the work of the Organisation for Economic Cooperation and Development, Food and Agriculture Organization of the United Nations, World Health Organization and the Codex Alimentarius Commission. These principles and guidelines were, however, applied within the context of the Australian and New Zealand food regulatory framework.

- *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.

- *The promotion of fair trading in food*

  The cost/benefit analysis in Section 4.1, lists a number of considerations that address fair trading with respect to soybean line CV127.

- *Any written policy guidelines formulated by the Ministerial Council*

  For GM foods, there are no relevant guidelines.

## 4.3 Implementation

The variation will take effect on gazettal.

# 5. References

Codex (2004) *Principles for the risk analysis of foods derived from modern biotechnology*. Report No. 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/_srcfiles/GM%20FINAL%20Sept%2007L%20_2_.pdf.

## Attachments

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

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

**Food Standards (Application A1064 – Food derived from Herbicide-tolerant Soybean Line 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 Line 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 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.

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 a Standard.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation[2], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the variation of a standard.

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

## 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. The purpose of the variation is to permit the sale or use in food of food derived from soybean line CV127 by including it in the Schedule to Standard 1.5.2.

## 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 A1064 included one round of public consultation following an assessment and the preparation of a draft variation to the Standard. A Report (which included the draft variation) was released on 24 January 2012 for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the variation to Standard 1.5.2 is likely to have a minor impact on business and individuals.

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

## 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 a permission for food derived from soybean line CV127 into the Schedule to Standard 1.5.2.