

25 May 2012
[11-12]

Approval Report – Application A1066

Food derived from Herbicide-tolerant Corn Line MON87427)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Monsanto Australia Limited (Monsanto) seeking permission for food derived from corn line MON87427 genetically modified to provide tolerance to the herbicide glyphosate.

On 16 January 2012, FSANZ sought submissions on a draft variation to a standard and published an associated report. FSANZ received 8 submissions.

FSANZ approved the draft variation to the Standard on 10 May 2012. The COAG Legislative and Governance Forum on Food Regulation¹ (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 document used to prepare this Report is available on the FSANZ website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1066food5286.cfm>

SD1: Safety Assessment Report (Approval)

1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Limited (Monsanto) on 16 August 2011. The Applicant requested a variation to Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code*, to permit the sale and use of food derived from genetically modified (GM) corn line MON87427, which is tolerant to the herbicide glyphosate.

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 corn line MON87427 is provided in Supporting Document 1 (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 corn line MON87427 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

A decision has been made to approve the draft variation to Standard 1.5.2 to include food derived from herbicide-tolerant corn line MON87427 in the Schedule.

2. Introduction

2.1 The Applicant

Monsanto Australia Limited is a technology provider to the agricultural and food industries.

2.2 The Application

Application A1066 – Food derived from herbicide-tolerant corn line MON87427, was submitted by Monsanto Australia Limited on 16 August 2011. It sought approval for food derived from line MON87427 under Standard 1.5.2 – Food produced using Gene Technology, in the Australia New Zealand Food Standards Code (the Code).

Corn line MON87427 is tolerant to the herbicide glyphosate. Tolerance was achieved by introducing the *cp4 epsps* gene, from the soil bacterium *Agrobacterium* sp. expressing the protein 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS). EPSPS proteins have been widely used to confer glyphosate tolerance in a range of GM crops. An added feature of the genetic modification in MON87427 is that the regulatory elements driving expression of the *cp4 epsps* gene permit no, or only very low, expression of the CP4 EPSPS protein in pollen tissue. This means that inbred lines containing the MON87427 transformation event can be sprayed with glyphosate at a critical developmental stage to produce male sterile female parents for use in hybrid seed production programmes.

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 corn line MON87427 is provided in SD1 and included the following key elements:

- a characterisation of the transferred genes, their origin, function and stability in the corn 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 corn line MON87427 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 were identified.

On the basis of the data provided in the present Application, and other available information, food derived from corn line MON87427 was considered to be as safe for human consumption as food derived from conventional corn cultivars.

3.2 Risk management

3.2.1 Labelling

In accordance with general labelling provisions, food derived from corn line MON87427 would have to be labelled as genetically modified if it contains novel DNA or novel protein, or has altered characteristics. Food from MON87427 does not have altered characteristics.

MON87427 itself is a dent corn and therefore is not a popcorn or sweet corn line, but it is possible that it could be used as a parent in the development of sweet corn lines. The grain from dent corns is mostly processed into refined products such as corn syrup and corn starch which, because of processing, contain negligible levels of any protein or DNA.

Similarly, in the production process for refined corn oil, novel protein and novel DNA are not likely to be present. Therefore such products derived from MON87427 would be unlikely to require labelling.

MON87427 corn products such as meal (used in bread and polenta) and grits (used in cereals) would be likely to contain novel protein and novel DNA, and if so, would require labelling. Sweet corn kernels containing the MON87427 event are also likely to 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 that 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.

The information that would be required to be given to the EAG would be the full sequence data for the insert and adjacent genomic DNA. Using this, any analytical laboratory would have the capability to develop a PCR detection method. This sequence information has been supplied by the Applicant, although it is currently CCI and would therefore have restricted access.

Since approval to grow corn MON87427 commercially has not yet been given in any country, food derived from this line would not yet be expected to enter the food supply.

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 on this Application.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response. While not all comments in submissions can be taken on board, 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 16 January and 27 February 2012. Eight submissions were received.

Responses to two general issues raised or implied, are available from the FSANZ website (see Table 1).

Submitters' concerns about environmental impacts of growing a GM crop, or the impact of GM crops on organic farming, have not been considered in this report since FSANZ does not have responsibility for assessing these. Similarly, the safe use of glyphosate has also not been considered other than in the context of any food products that may be derived from a crop sprayed with the herbicide.

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Lack of faith in the FSANZ safety assessment	Suzanne Roth	<p>A detailed description of the process involved in the FSANZ safety assessment of GM foods is available on the FSANZ website at http://www.foodstandards.gov.au/srcfiles/GM%20Foods_text_pp_final.pdf</p> <p>The conduct of the safety assessment is subject to strict requirements outlined in the <i>Application Handbook</i>². In turn, these requirements are guided by concepts and principles developed through the work of the Organisation for Economic Cooperation and Development, Food and Agriculture Organization of the United Nations, World Health Organisation and Codex Alimentarius Commission.</p>
Labelling of GM food	Suzanne Roth	<p>Responses are available on the FSANZ website at Appendix 3: Safety Assessment of Genetically Modified Foods http://www.foodstandards.gov.au/srcfiles/GM%20Foods_text_pp_final.pdf</p> <p>Frequently Asked Questions on GM foods Part III. Labelling of GM Foods http://www.foodstandards.gov.au/foodmatters/gmfoods/frequentlyaskedquest3862.cfm</p> <p>GM Labelling Review Report http://www.foodstandards.gov.au/newsroom/publications/gmlabellingreviewrep2460.cfm</p>

One issue specific to the assessment of corn line MON87427 was raised and is addressed below.

3.2.3.1 The safety of glyphosate and its residues³

Michelle Denise and Caroline Reid, both private submitters, were concerned that the safety assessment failed to address any toxicity consideration associated with the use of the herbicide glyphosate.

As with any GM application involving herbicide tolerance, FSANZ needed to consider, in Application A1066, two separate aspects relating to two separate Standards in the Code.

- In relation to Standard 1.5.2, it is paramount to consider in the safety assessment whether novel metabolites are produced after the herbicide is applied and, if so, whether these are present in the final food and whether their presence raises any toxicological concerns.

In particular, the assessment considers whether appropriate health-based guidance values (i.e. Acceptable Daily Intake [ADI] or Acute reference Dose [ARfD]) need to be established. In the case of MON87427, data were provided to show that no novel metabolites are produced as a result of the genetic modification. Therefore, no further consideration is necessary relating to Standard 1.5.2.

² The *Application Handbook* is available at <http://www.foodstandards.gov.au/foodstandards/changingthecode/applicationshandbook.cfm>

³ A pesticide residue is any specified substance in food, agricultural commodities or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities that are considered to be of toxicological significance.

- A separate consideration involves Standard 1.4.2 – Maximum Residue Limits. In the case of food entering Australia via imports (that is, the crop will not be grown in Australia), it may be necessary for FSANZ to amend the Maximum Residue Limit (MRL). Standard 1.4.2 does not apply to New Zealand. Instead, the setting of MRLs for imported foods in that country is considered by the Ministry for Agriculture and Forestry (for inclusion in Maximum Residue Limits of Agricultural Compounds – see <http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm>).

Any food products (whether derived from GM or non-GM sources) sold in both Australia and New Zealand must not have chemical residues greater than the relevant MRL. The MRL for a herbicide is derived from data collected from field trials conducted under Good Agricultural Practice and is a legally enforceable limit. The results from field trials are used to establish an MRL only if the estimated dietary exposures to residue(s) do not exceed the ADI or ARfD for that residue. In undertaking a risk-based assessment to support inclusion of an MRL, the key issue is whether, in the context of the Australian/New Zealand diet, exposures to any chemical residues in the food remain below the health-based guidance values. Where necessary to confirm that the level set is not an undue hazard to human health, FSANZ would undertake a dietary exposure assessment. An ADI of 0.3 mg/kg body weight for glyphosate has already been established.

For GM food applications, the process of considering MRLs is separate from the safety considerations under Standard 1.5.2 and, at the time this report was prepared, still needs to be undertaken with regard to corn line MON87427. Variations to both Standard 1.5.2 and Standard 1.4.2 (or the NZ Maximum Residue Limits of Agricultural Compounds) if appropriate, would need to be gazetted before food derived from corn line MON87427, which may have been treated with glyphosate, could legally be sold in Australia or New Zealand.

3.3 Risk communication

FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media tools and the *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 A1066 is available on the website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1066food5286.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 corn line MON87427 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 corn line MON87427.

- Food derived from corn line MON87427 is equivalent to that derived from the conventional counterpart and other commercially available corn cultivars in terms of its safety for human consumption and nutritional adequacy.
- Labelling of food derived from corn line MON87427 will be required in the ingredients list or in conjunction with the name of the food, if it contains novel DNA or novel protein.
- There were no measures that would be more cost-effective than a variation to Standard 1.5.2 and could achieve the same end.

4.1 Section 29

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 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 corn products as there would be no restriction on imported foods containing corn line MON87427.

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

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

Government: Benefit that if corn line MON87427 was detected in corn imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of corn line MON87427 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 corn derivatives would benefit as foods derived from corn line MON87427 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 corn products or imported foods manufactured using corn derivatives.

Possible cost to food industry as some food ingredients derived from corn line MON87427 would be required to be labelled.

As food from corn line MON87427 has been found to be as safe as food from conventional cultivars of corn, rejecting the variation would offer little benefit to consumers, as approval of corn line MON87427 by other countries could limit the availability of imported corn products in the Australian and New Zealand markets. In addition, this option would result in the requirement for segregation of any products containing corn line MON87427 from those containing approved corn lines which would be likely to increase the costs of imported corn-derived foods. Also, rejection of the draft variation was considered likely to be inconsistent with Australia's and New Zealand's WTO obligations.

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

4.1.2 Other measures

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

4.1.3 Relevant New Zealand standards

Standard 1.5.2 applies in New Zealand.

4.1.4 Any other relevant matters

Monsanto submitted a food and feed safety and nutritional assessment summary for MON87427 to the US Food and Drug Administration in December 2010 and also requested a Determination of Nonregulated Status for MON 87427, including all progeny derived from crosses between MON 87427 and other corn lines, from the Animal and Plant Health Inspection Service of the US Department of Agriculture in October 2010.

Applications have also been submitted to:

- the Canadian Food Inspection Agency and Health Canada in January 2011
- the Korean Food and Drug Administration and Rural Development Administration in June 2011
- Japan's Ministry of Environment, Ministry of Health, Labour, & Welfare, and Ministry of Agriculture, Forestry & Fisheries in May 2011, June 2011 and July 2011 respectively
- Taiwan's Department of Health in June 2011

- the Philippines Bureau of Plant Industry in July 2011
- Singapore's Agri-Food and Veterinary Authority (Genetic Modification Advisory Committee) in October 2011
- the Colombian Institute for Agriculture and National Institute for the Surveillance of Drugs and Food in December 2011.

No approvals for any of these submissions have been made to date.

The Applicant has indicated that submissions are likely to be made to a number of additional governmental regulatory agencies including those in China, Mexico and the European Union.

The Applicant has indicated that there is currently no intention to apply for approval to cultivate MON87427 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.

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 corn line MON87427 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 corn line MON87427 is considered as safe and wholesome as food derived from commercial, conventional corn 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 corn line MON87427 would 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 labelling provision and the requirement for detection methodology (see Section 3.2.2) are designed to address 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 corn line MON87427.

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

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

- Approved variation to the *Australia New Zealand Food Standards Code*
- Explanatory Statement

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



Food Standards (Application A1066 – Food derived from Herbicide-tolerant Corn MON87427) 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 X

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

1 Name

This instrument is the *Food Standards (Application A1066 – Food derived from Herbicide-tolerant Corn MON87427) 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–

	2.x	Food derived from herbicide-tolerant corn line MON87427	
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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).⁴

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 A1066 which seeks permission for the sale and use of food derived from herbicide-tolerant corn line MON87427. 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 Regulation⁴, 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 sunseting 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 corn line MON87427 is not currently permitted for sale or use in food. Therefore, FSANZ is proposing to vary Standard 1.5.2 to permit the sale, or use in food, of food derived from corn line MON87427 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 A1066 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 16 January 2012 for a six-week consultation period.

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

⁴ 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 food derived from corn line MON87427 into the Schedule to Standard 1.5.2.