

4 November 2015
[28–15]

Approval Report – Application 1110

Food derived from Insect-protected Soybean Line MON87751

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Monsanto Australia Ltd seeking permission for food derived from soybean line MON87751, which is genetically modified to provide protection against key lepidopteran pests of soybean.

On 15 July 2015, FSANZ sought submissions on a draft variation to Standard 1.5.2 and published an associated report. FSANZ received seven submissions.

FSANZ approved the draft variation on 28 October 2015. The Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) was notified of FSANZ’s decision on 3 November 2015.

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

¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting documents

The following document, which informed the assessment of this Application, is available on the FSANZ website at

<http://www.foodstandards.gov.au/code/applications/Pages/A1110GMsoybeanMON87751.aspx>

SD1 Safety Assessment Report (at Approval)

Executive summary

All references to the *Australia New Zealand Food Standards Code* (the Code) in this report and related SD are to the revised Code which takes effect and replaces the current Code on 1 March 2016. FSANZ considers it is unnecessary to amend the current Code because the gazettal of any draft variation is not expected until close to this date, if no review of FSANZ's decision is requested by Ministers.

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Ltd on 20 February 2015. The Applicant requested a variation to current 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 a genetically modified (GM) soybean line that is protected against lepidopteran pests.

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in s 18 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), is the protection of public health and safety. Accordingly, the safety assessment is a central part of considering an application.

The safety assessment of insect-protected soybean line MON87751 (also referred to as MON87751) 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 MON87551 is considered to be as safe for human consumption as food derived from conventional soybean cultivars.

The FSANZ Board has approved the draft variation to Schedule 26 of the revised Code (commencing on 1 March 2016) to include food derived from insect-protected soybean line MON87751.

1 Introduction

1.1 The Applicant

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

1.2 The Application

Application A1110 was submitted by Monsanto Australia Ltd on 20 February 2015. It seeks approval for food derived from insect-protected soybean line MON87751 with OECD Unique Identifier MON-87751-7 (also referred to as MON87751).

MON87751 has been modified such that it is protected against lepidopteran pests of soybean.

Protection against lepidopteran insect pests is achieved through expression of two Cry proteins (Cry1A.105 and Cry2Ab2) encoded by the *cry1A.105* and *cry2Ab2* genes derived from the common soil bacterium *Bacillus thuringiensis*. The safety of the Cry1A.105 and Cry2Ab2 proteins has previously been assessed by FSANZ.

1.3 The current Standard

FSANZ completed a review of the Code in 2015 and the revised Code will commence on 1 March 2016. The current Standard 1.5.2, which sets out permission and conditions for the sale and use of food produced using gene technology (a GM food), is replicated in the revised Code with the relevant standard being Schedule 26.

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. Foods that have been assessed and approved are listed in the Schedule to Standard 1.5.2 in the current Code and Schedule 26 of the revised Code.

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 (as defined in Standard 1.5.2) is present in the final food, or the food has altered characteristics. In the latter case, the Standard also allows for specific additional labelling about the nature of the altered characteristics.

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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved without change. This draft variation is only for the revised Code since it comes into operation and replaces the current Code on 1 March 2016. FSANZ believes it is unnecessary to amend the current Code as gazettal is expected close to this time, if no review of that decision is requested by Ministers. The variation to the revised Code comes into effect on 1 March 2016. The approved draft variation is at Attachment A.

An explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

2 Summary of the findings

2.1 Summary of issues raised in submissions

2.1.1 General Issues

A total of seven submissions were received, four of which supported the variation to Schedule 26. Of these submissions, some raised issues that are outside the scope of FSANZ's regulatory area e.g. public perception of GM food; opinions about biotechnology developers; and environmental issues. In the latter case, issues related to the growing of GM crops and any possible effects on the environment are considered in Australia by the Office of the Gene Technology Regulator, and in New Zealand by the Environmental Protection Authority.

Responses to five general issues, raised or implied in submissions, are provided in Table 1.

Table 1: Summary of general issues raised in submissions

Issue	Raised by	FSANZ response
<p>Concerns with the safety of GM food and the FSANZ safety assessment process</p>	<ul style="list-style-type: none"> • Physicians & Scientists for Global Responsibility (PSGR) • GM-Free Australia Alliance (GMFAA) 	<p>The approach used by FSANZ to assess the safety of GM food is based on core principles developed almost 20 years ago and published as guidelines by the Codex Alimentarius Commission (Codex, 2003; Codex, 2004). Over time, the assessment protocol has been the subject of scientific scrutiny and has proved to be a robust approach for whole food safety assessments. It is widely adopted and implemented around the world. While philosophical opposition to the technology remains, consumers can be confident that GM foods assessed under the protocol and approved for food use are as safe as their conventional counterparts.</p> <p>In 2008, an external review of the FSANZ GM food safety assessment procedure was undertaken. The findings of the review are available at http://www.foodstandards.gov.au/consumer/gmfood/pages/revi ewofgeneticallym4394.aspx.</p> <p>Studies cited as evidence of safety concerns with certain GM foods have been examined by FSANZ and other scientific experts around the world. The studies have been subject to significant scientific criticism and generally are not supported. Responses to several recent publications are available on the FSANZ website (http://www.foodstandards.gov.au/consumer/gmfood/adverse/P ages/default.aspx).</p>

Issue	Raised by	FSANZ response
<p>Lack of consideration of long term feeding studies in the safety assessment</p>	<ul style="list-style-type: none"> • GMFAA 	<p>There is general consensus among food regulators that the key focus in determining the safety of a GM food is the comparative compositional analysis. This concept was first considered in 1993 (OECD 1993) and there has not been any change to this thinking (Herman et al. 2009). The compositional analysis of grain from line 4114 showed that it is compositionally equivalent to grain from conventional corn varieties.</p> <p>In 2007, FSANZ convened a workshop to formally examine the usefulness of animal feeding studies to support the safety assessment of GM foods (http://www.foodstandards.gov.au/consumer/gmfood/Pages/roleofanimalfeedings3717.aspx). The conclusion was that such studies do not contribute meaningful information on the long-term safety of a GM food, with the possible exception of a food in which the modification introduced a desired nutritional change. Therefore, for most GM foods, including those derived from line 4114, feeding trials of any length are unlikely to contribute any further useful information to the safety assessment and are not warranted. There are also concerns about the unethical use of animals for feeding studies in the absence of any clearly identified compositional differences (Rigaud 2008; Bartholomaeus et al. 2013).</p>
<p>The safety of ingesting transgenes</p> <p>Horizontal gene transfer</p>	<ul style="list-style-type: none"> • PSGR 	<p>DNA is a natural component of the human diet, being present to varying degrees in foods derived from plants and animals, especially those that have undergone minimal processing. There is no difference in terms of risk between recombinant DNA and the DNA already present in our diet.</p> <p>These issues has been considered in detail by FSANZ and a summary is available on the FSANZ website http://www.foodstandards.gov.au/consumer/gmfood/recombinantdna/Pages/default.aspx.</p>
<p>Concern with ingestion of Cry proteins</p>	<ul style="list-style-type: none"> • PSGR • GMFAA 	<p>There has been widespread consideration about the safety of GM food crops modified to contain Cry genes (see e.g. Mendelsohn et al. 2003; Hammond and Koch 2012; Koch et al. 2015) and the conclusion reached through assessment of the data available is that <i>Bt</i> crops do not pose a safety concern.</p> <p>As shown by data presented in the SD1 (Table 4), levels of the two Cry proteins in the edible part (i.e. seed) of MON87751 are extremely low. Additionally, both proteins are readily broken down firstly, during the processing (heat treatment) necessary to inactivate the toxicants and anti-nutritional factors present naturally in all soybeans and secondly, during digestion if any intact proteins remain after processing.</p> <p>It is also relevant to note that products derived from <i>B. thuringiensis</i> have been sprayed on crop plants for 50 years. The effect of these products on human health and the environment was the subject of a critical review by the WHO International Programme on Chemical Safety (WHO 1999). The review concluded that '<i>B. thuringiensis</i> products are unlikely to pose any hazard to humans or other vertebrates or the great majority of non-target invertebrates' Products containing <i>Bt</i> are approved for use on crops in Australia and New Zealand and in both countries there is an exemption from MRLs when <i>Bt</i> is used as an insecticide.</p>

Issue	Raised by	FSANZ response
<p>Current GM labelling is inadequate</p>	<ul style="list-style-type: none"> • GMFAA 	<p>Only those GM foods assessed by FSANZ as safe are approved for sale. The labelling of approved GM foods is therefore not for safety reasons. Australia's and New Zealand's GM food labelling laws are some of the most extensive in the world. They are based on the presence of GM material or altered characteristics in the final food ('product-based' labelling) rather than 'process-based' labelling which is based solely on the production method, irrespective of the presence of GM material or altered characteristics in the final food. This approach was designed to be practical and enforceable.</p> <p>The current labelling laws for GM foods in Australia and New Zealand were decided on by the Australia and New Zealand Food Regulation Ministerial Council (now known as The Australia and New Zealand Ministerial Forum on Food Regulation – the Forum). The Forum's decision to base GM labelling on the final food product sought to balance the need for consumers to be provided with meaningful information, against the need for such requirements to be practical and enforceable.</p> <p>In December 2011, the Forum responded to the recommendations contained in <i>Labelling Logic: Review of food labelling law and policy (2011)</i>. In its response, the Forum supported the continuation of the current GM labelling provisions in the Food Standards Code and agreed not to pursue any additional regulatory requirements. Further information on the review and the government response is available from the Review of Food Labelling Law and Policy website at http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/Content/home.</p>

2.1.2 Specific issues raised

2.1.2.1 GM soy in honey

The Australian Honey Bee Industry Council (AHBIC) was concerned that soy flour, a supplemental feed for honey bees, may contain GM soy. This GM soy may then be found in Australian honey exported to the European Union and would make the honey unsaleable in Europe unless food from the GM soy line had been approved in the EU. The AHBIC requested that food from MON87751 not be approved in Australia, unless it was also approved in the EU.

Response: It is noted that soy flour is not used exclusively by the honey bee industry and could potentially be used in baked goods, as well as providing the basis for some soymilks and textured vegetable protein. As indicated, in Section 2.3.1, GM soy flour would require labelling and, hence, its use could be avoided.

GM food approvals made by FSANZ are based on the safety of the food, and that approval cannot be contingent upon, or delayed to coincide with, a decision being reached on that food in another jurisdiction. As indicated in Table 2, the Applicant has submitted a food application to the European Food Safety Authority (EFSA) for MON87751 and this is currently under assessment. If the AHBIC has concerns about marketing issues associated with asynchronous approvals between Australia and the EU, these are best addressed through discussions with the Applicant, who ultimately decides on the timing of applications to various markets.

2.1.2.2 Labelling of 'second generation' products

The Food Technology Association of Australia was concerned that food products derived from progeny produced by conventionally breeding MON87751 with other lines would not require labelling.

Response: The labelling requirement set out in Standard 1.5.2 applies equally to food produced from the approved line as well as any plant descended from the approved line as a result of conventional breeding.

2.2 Safety assessment

The safety assessment of MON87751 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 soybean genome
- characterisation of novel nucleic acids and protein in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes
- the potential for any newly expressed protein to be either allergenic or toxic in humans.

The assessment of MON87751 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.

No potential public health and safety concerns have been identified. Minor typographical errors, identified during the Call for Submissions, have been corrected in the SD1.

Based on the data provided in the present Application, and other available information, food derived from MON87751 is considered to be as safe for human consumption as food derived from conventional soybean cultivars.

2.3 Risk management

2.3.1 Labelling

In accordance with Standard 1.5.2, food derived from MON87751 would be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein, or if it has altered characteristics. MON87751 does not have altered characteristics.

MON87751 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. Processing during production means novel protein and novel DNA are not likely to be present in the oil; in the absence of novel protein and novel DNA, refined oil from MON87751 would be exempt from labelling under section 1.5.2-4 of Standard 1.5.2 in the revised Code. Other products such as protein concentrate, protein isolate and textured flour are likely to contain novel protein or novel DNA and, if so, would require labelling.

2.3.2 Detection methodology

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee² to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food derived from gene technology (GM applications).

The EAG indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the Applicant for A1110 and hence satisfies the requirement for detection methodology in the FSANZ *Application Handbook* (FSANZ 2013).

2.4 Risk communication

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

Public submissions were invited on a draft variation which was released for public comment between 15 July and 26 August 2015.

The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media tools and the publication, Food Standards News. Subscribers and interested parties were also notified.

A total of seven submissions were received, of which three objected to the proposed variation. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. All comments are valued and contribute to the rigour of the safety assessment. Every submission on this application was considered by the FSANZ Board.

Documents relating to Application A1110, including submissions received, are available on the FSANZ website.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 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 of the OBPR to assess if a Regulatory Impact Statement is required for the approval of additional genetically modified foods (reference 12065). The exemption was provided as applications relating to genetically modified food are considered as minor, machinery and deregulatory in nature.

FSANZ undertook a cost benefit analysis (see below). The analysis concluded the direct and indirect benefits that would arise from a food regulatory measure, varied as a result of Application A1110, outweigh the costs to the community, Government or industry.

² Now known as the Implementation Subcommittee for Food Regulation

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. It is noted that the cost/benefit analysis is based on MON87751 (and any lines containing the MON87551 event) being approved for growing in other countries (see section 2.5.1.4 below).

Consumers: Broader availability of imported soybean products since MON87751 is approved for commercial growing in other countries, and there would therefore be no restriction on imported foods containing this line.

For those soybean line MON87751 products containing novel DNA or novel protein, appropriate labelling would allow consumers wishing to avoid these products to do so.

Since MON87751 is approved for commercial growing in overseas countries it can be used in the manufacture of products using co-mingled soybean seed. This means that there would be no cost involved in having to exclude MON87751 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 soybean seed.

Government: If MON87751 was detected in food imports, approval would ensure compliance with the Code and prevent any trade disruption on regulatory grounds.

Approval would result in no conflict with WTO responsibilities.

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 MON87751 would be permitted under the Code, allowing broader market access and increased choice in raw materials.

The segregation of seed of MON87751, as for any GM crop, will be driven by industry, based on market preferences. Implicit in this will be a due regard to the costs of maintaining various levels of purity.

Retailers may be able to offer a broader range of soybean products or imported foods manufactured using soybean derivatives.

There may be additional costs to the food industry as food ingredients derived from MON87751 would require the 'genetically modified' labelling statement if they contain novel DNA or novel protein.

As food from MON87751 has been found to be as safe as food from conventional cultivars of soybean, not preparing a draft variation would offer little benefit to consumers, as approval of MON87751 by other countries could limit the availability of imported soybean products in the Australian and New Zealand markets. In addition, this option would result in the requirement for segregation of any products containing MON87751 from those containing approved soybean lines which would be likely to increase the costs of imported soybean-derived foods.

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

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of A1110.

2.5.1.3 Any relevant New Zealand standards

Standard 1.5.2 applies in New Zealand.

2.5.1.4 Any other relevant matters

The Applicant has submitted applications for regulatory approval of MON87751 to a number of other countries, as listed in Table 2. Some of these have been finalised as indicated.

Table 2: List of countries to whom applications for regulatory approval of MON87751 have been submitted

Country	Agency	Type of approval sought	Status
USA	Department of Agriculture	environment ¹	Authorised 17/10/2014
	Food & Drug Administration	food/feed	Consultation completed 27/05/2015
	Environmental Protection Agency	environment ¹	Authorised 27/04/2015
Canada	Food Inspection Agency	environment ¹ /feed	Authorised 31/10/2014
	Health Canada	food	Authorised 31/10/2014
Japan	Ministry of Health, Labour and Welfare	food	Under assessment
	Ministry of Agriculture, Forestry & Fisheries	feed	Under assessment
	Ministry of Agriculture, Forestry & Fisheries; Ministry of the Environment	environment	Under assessment
Korea	Ministry of Food and Drug Safety	food	Under assessment
	Rural Development Administration	feed	Under assessment
China	Ministry of Agriculture	food	Under assessment
Taiwan	Ministry of Health & Welfare	food/feed	Under assessment
Argentina	National Advisory Commission on Agriculture Biotechnology (CONABIA)	environment	Under assessment
	National Service of Agriculture & Cattle Sanitary & Food Safety (SENASA)	food/feed	Under assessment
Brazil	National Biosafety Technical Committee (CTNBio)	food	Under assessment
Europe	European Food Safety Authority (EFSA)	food	Under assessment

¹an authorisation for 'environment' indicates the line could be (but may not necessarily be) grown commercially in that country

It is the Applicant's stated intention that lines containing event MON87751 be commercially cultivated predominantly in South America (e.g. Argentina and Brazil). There is currently no intention to apply for approval to cultivate lines containing this event 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.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

Food derived from MON87751 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 MON87751 is considered as safe and wholesome as food derived from other commercial soybean cultivars.

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

In accordance with existing labelling provisions to enable informed consumer choice, food derived from MON87751 would have to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see discussion in section 2.3.1).

2.5.2.3 The prevention of misleading or deceptive conduct

The requirement for detection methodology (see section 2.3.2) is designed to address this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex 2004). Based on these principles, the risk analysis undertaken for MON87751 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. MON87751 is a new food crop designed to expedite future breeding efforts and provide growers with an alternative pest management strategy.

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

Not applicable

- **any written policy guidelines formulated by the Ministerial Council³**

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

References

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³ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

Attachments

- A. Approved draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)
- B. Explanatory Statement

Attachment A – Approved draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)



Food Standards (Application A1110 – Food derived from Insect-protected Soybean Line MON87751) 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 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.

1 Name

This instrument is the *Food Standards (Application A1110 – Food derived from Insect-protected Soybean Line MON87751) Variation*.

2 Variation to a Standard in the *Australia New Zealand Food Standards Code*

The Schedule varies Schedule 26 of the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions — 2014 Revision.

SCHEDULE

[1] Item 7 in the table to subsection S26—3(4) of Schedule 26 is varied by inserting after item 7(o)

“

(p) insect-protected soybean line MON87751

”

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 A1110 which seeks permission for the sale and use of food derived from insect-protected soybean line MON87751 (MON87751). The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation⁴, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

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

2. Purpose

The variation inserts a reference to insect-protected soybean line MON87751 into Schedule 26 of the Code in order to permit the sale, or use in food, of food derived from that soybean 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 A1110 included one round of public consultation following an assessment and the preparation of a draft variation.

A Regulation Impact Statement was not required because the Application is 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.

⁴ convening as the Australia and New Zealand Food Regulation Ministerial Council

6. Variation

Item [1] inserts item 7(p) into the table to subsection S26—3(4) of Schedule 26. The new item refers to insect-protected soybean line MON87751. The effect of the variation is to permit in accordance with Standard 1.5.2 the sale and use of food derived from that soybean line.