26 March 2012
[7-12]

Approval Report – Application A1063

Food derived from Herbicide-tolerant Soybean Line MON87708

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Monsanto Australia Limited (Monsanto) seeking permission for food derived from soybean line MON87708 genetically modified to provide tolerance to the herbicide dicamba.

On 18 October 2011, FSANZ sought submissions on a draft variation to a standard and published an Assessment Report. FSANZ received 15 submissions.

FSANZ approved the draft variation to the Standard on 8 March 2012. The COAG Legislative and Governance Forum on Food Regulation[1] (the Forum) was notified of FSANZ's decision on 23 March 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/applicationa1063food5198.cfm

SD1: Safety Assessment Report (Approval)

1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Limited (Monsanto) on 27 May 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 MON87708, which is tolerant to the herbicide dicamba.

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 MON87708 is provided in Supporting Document 1. 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 MON87708 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 MON87708 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 A1063 – Food derived from herbicide-tolerant soybean line MON87708, was submitted on 27 May 2011. It sought approval for food derived from line MON87708 under Standard 1.5.2 – Food produced using Gene Technology, in the *Australia New Zealand Food Standards Code* (the Code).

Soybean line MON87708 is tolerant to the herbicide dicamba. This is achieved through introducing the *dmo* gene, from the soil bacterium *Stenotrophomonas maltophilia*, expressing the protein dicamba mono-oxygenase (DMO). DMO rapidly demethylates dicamba to a non-herbicidal metabolite, thereby allowing the plant to remain functional in the presence of dicamba. FSANZ has not previously assessed this protein.

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

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 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 MON87708 is provided in the supporting document (SD 1) 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 MON87708 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 soybean line MON87708 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 general labelling provisions, food derived from soybean line MON87708, if approved, would be required to be labelled as genetically modified if it contains novel DNA or novel protein, or has altered characteristics. MON87708 does not have altered characteristics.

Soybean MON87708 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 (Liu *et al*., 1995). The main food product from field soybean is oil. Because the oil production process results in a highly refined product, both novel protein and novel DNA are unlikely to be present; the oil is therefore 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 form an Expert Advisory Group (EAG) involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions, to 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 MON87708, this methodology involves the use of the polymerase chain reaction for DNA detection. Because of the technology involved, this detection method is likely to be restricted to specialist laboratories.

Since Monsanto 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/).

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 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 18 October and 29 November 2011. Fifteen submissions were received.

Responses to a number of general issues raised, such as data used to inform the Safety Assessment, labelling of GM foods and the results of a GM pea study[2] are available from the FSANZ website (see Table 1). In relation to general comments made about the way in which FSANZ conducts a safety assessment, it should be noted that the data submitted by an Applicant and the conduct of the studies are subject to strict requirements outlined in the *Application Handbook.* 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.

Submitters concerns about environmental impacts of growing a GM crop or safe use of dicamba have not been considered in this report since FSANZ does not have responsibility for assessing these other than in the context of a consideration of any food products that may be derived from a crop sprayed with a herbicide.

[2] Prescott, V.E.; Campbell, P.M.; Moore, A.; Mattes, J.; Rothenberg, M.E.; Foster, P.S.; Higgins, T.J.V.; Hogan, S.P. (2005). Transgenic expression of bean α-amylase inhibitor in peas results in altered structure and immunogenicity. Journal of Agricultural and Food Chemistry 53: 9023 – 9030.

Table 1: Summary of general issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Data used to inform the Safety Assess.	• Soil & Health Association of New Zealand • GE Free New Zealand	Responses are available on the FSANZ website at: http://www.foodstandards.gov.au/foodmatters/gmfoods/ Data submitted by an Applicant and the conduct of the studies are subject to strict requirements outlined in the *Application Handbook*[3]. These requirements are based on widely recognised principles for assessing the safety of whole foods which have been established since the 1990s at the international level by bodies such as the Codex Alimentarius Commission, the WHO and the OECD. Similar assessment procedures are followed in Canada, Japan, the EU and the USA.
Labelling of GM food	GE Free New Zealand	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 Frequently Asked Questions on GM foods Part III. Labelling of GM Foods http://www.foodstandards.gov.au/foodmatters/gmfoods/frequentlyaskedquest3862.cfm GM Labelling Review Report http://www.foodstandards.gov.au/newsroom/publications/gmlabellingreviewrep2460.cfm
GM pea study	Veronika Sain – private submitter	Response is available on the FSANZ website at http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets2005/geneticallymodifiedf3097.cfm

A number of issues specific to the assessment of soybean line MON87708 were raised and are addressed below.

3.2.4.1 The safety of dicamba and its residues[4]

The NSW Food Authority and a private submitter were concerned that the Safety Assessment neither contained information on the residues that may be produced in MON87708 as a result of spraying with dicamba, nor addressed MRL issues.

As for any GM application involving herbicide tolerance, FSANZ needed to consider, in Application A1063, 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.

[3] The *Application Handbook* is available at (http://www.foodstandards.gov.au/foodstandards/changingthecode/applicationshandbook.cfm).

[4] 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.

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 MON87708, 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.

- 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)[5]. Standard 1.4.2 of the Code does not however 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. As stated in the Safety Assessment, an ADI of 0.03 mg/kg body weight for dicamba has already been established. This is the same level established for New Zealand.

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 soybean line MON87708. 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 soybean line MON87708, which may have been treated with dicamba, could legally be sold in Australia or New Zealand.

3.2.4.2 Issues raised by the Centre for Integrated Research in Biosafety (INBI)

INBI made a submission comprising a total of nine recommendations covering 12 main points. These points are summarised and addressed below. As a general comment, in response to most of these points, and especially to those in which further studies are requested, it must be stated that the cumulative evidence from all the studies associated with soybean MON87708, point to comparable safety with its conventional soybean counterpart. FSANZ considers the data supplied by the Applicant sufficient to establish the safety of the food, and satisfy the requirements of the FSANZ *Application Handbook*.

While it may be technically possible to generate data to answer an infinite number of interesting research questions, FSANZ only requests data that it deems necessary to draw a conclusion about the safety of a GM food. This particularly applies to points iv, v, viii and xii below.

[5] For GM crops grown in Australia, establishment of an MRL is done through collaboration with the Australian Pesticides and Veterinary Medicines Authority (APVMA)

The INBI submission also places great emphasis on points in the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*. The Codex document is a guideline and its considerations are therefore not mandatory for the safety assessment of GM foods. The FSANZ *Application Handbook* incorporates many but not all of the Codex recommendations.

i. The Applicant and FSANZ have misused the term 'biotechnology'-derived.

The use and interpretation of this terminology is not relevant to the risk assessment of MON87708.

ii. The donor organism Stenotrophomonas maltophilia has not been discounted as a disease-causing organism.

The Safety Assessment acknowledges that *S. maltophilia* has been implicated in infections in immuno-compromised hospital patients. There is, however, no suggestion that the DMO gene isolated from the organism is associated with this pathogenicity.

iii. The fact that DMO activity is undetectable at temperatures higher than 55^{o} C does not mean that the protein doesn't have the potential to cause harm when it is inhaled in flour.

Consideration of the inhalation (occupational exposure) of MON87708 flour during its handling, production or addition to other foods is beyond the scope of a FSANZ safety assessment. Safe Work Australia, is a body established by the Commonwealth Government to develop, facilitate and implement a national approach to occupational health and safety. It produces occupational health guides that cover a whole range of issues including atmospheric contaminants such as grain dust and flour that may lead to problems such as occupational asthma. There is, however, no specific consideration of individual types of flours (e.g. soy flour or wheat flour) or whether a flour is derived from a GM source. Safe Work Australia is a national policy body, not a regulator of work health and safety. The Commonwealth, states and territories have responsibility for regulating and enforcing work health and safety laws in their jurisdiction.

It is important to note that the potential allergenicity and toxicity of any novel proteins in MON87708 have been assessed. The heat lability of DMO is only one aspect considered in relation to allergenicity and toxicity and, for example, the bioinformatic analyses provide information on whether an introduced protein shares any amino acid sequence similarity with known protein toxins and allergens. It is relevant to note that the databases interrogated in the bioinformatic analyses include sequences from inhaled proteins.

The weight of evidence from a number of studies is that no safety concerns have been identified and food derived from MON87708 is considered to be as safe for human consumption as food derived from non-GM soybean varieties.

iv. The study testing the substrate specificity of DMO is insufficient.

The Applicant tested five potential endogenous substrates, none of which was utilised by DMO. Taken together with evidence from the results of other studies, there is no indication that the presence of DMO in MON87708 has an unintended effect.

v. Phenotypic and agronomic data on MON87708 were collected in only one season.

Phenotypic stability was tested over a number of generations. Field trials for compositional analyses were grown at five field sites across North America during the 2008 growing season. This was considered sufficient to allow assessment of MON87708 over a variety of geographical/climatic conditions relevant to commercial soybean production.

vi. In the study comparing the endogenous allergenicity of MON87708 and wild type soybean there is no taking into account the reaction of people who have never been exposed to MON87708.

The purpose of the study was not to distinguish between the allergenic potentials of conventional soybean and line MON87708 but to indicate whether the levels of endogenous allergens in the two are comparable. The potential allergenicity of the novel protein (DMO) was determined in a different assessment.

The fact that no differences were detected neither proves nor disproves the safety of soybean MON87708 but does indicate that, with regard to IgE binding using sera from soybean allergic individuals, soybean MON87708 elicits a response similar to conventional soybean.

vii. A rat feeding study submitted by the Applicant in a dossier to the European Food Safety Authority was not included in the dossier submitted to FSANZ.

The FSANZ *Application Handbook* clearly states that an animal feeding study is required "if the compositional analysis indicates biologically significant changes to the levels of certain nutrients". In the case of MON87708, no such changes were indicated and therefore a feeding study was not required by FSANZ.

However, if an animal feeding study is available the *Application Handbook* states it **should** be submitted to FSANZ. On request, the Applicant provided two feeding studies, and a summary of the relevant information from these has now been added to the safety assessment. No alteration to the conclusion of the safety assessment was necessary.

viii. The antigen used to raise anti-DMO antibody and the technique used to purify the antibody have not been described. It is possible that the immunoreactivity assays have failed to detect potential DMO isoforms.

Protein isoforms are variants of a single polypeptide. In nature they often occur as a result of the presence of multiple genes arising from a single ancestor gene, a possibility that is excluded in GM plants in which a specific gene sequence has been inserted. Isoforms may also occur as a result of elongation/truncation of the full length amino acid sequences or due to post-translational modifications such as glycosylation.

Elongation or truncation of a polypeptide, if significant (i.e. greater than approximately 5% of the full length number of amino acids), is readily detected by Western blot analysis. Since a polyclonal antibody (as used in the Western blots described in the studies) binds to a number of epitopes, elongation of the protein will not affect antibody binding. Likewise, since it is highly unlikely to cause loss of all epitopes, truncation is unlikely to go undetected.

A plant extract separated by SDS-PAGE and then probed with the antibody will show one or more bands corresponding to the expected form of the protein as well as any isomers that may be produced by elongation or truncation.

This is exactly what occurred when the extract from MON87708 revealed two monomers, DMO and the elongated DMO+27 protein isoform in the Western blot.

In the glycosylation study, neither the DMO nor the DMO+27 monomers were shown to be glycosylated. On the basis of the available evidence, knowledge of the source of the antigen used to raise the DMO antibody would not alter the conclusions reached about the safety of food derived from MON87708.

ix. Protein characterisation studies lack a description of detection limits for e.g. the immunoblot analysis, MALDI-TOF analysis and glycosylation analysis.

Knowing the limit of detection of an analytical technique is important only where there are no relative comparisons or weight of evidence to support a conclusion.

- In the case of the immunoblot analysis, a positive recognition was obtained for both the DMO and DMO+27 proteins. Knowing (or not knowing) the limit of detection does not in any way alter the conclusion that the identity of the proteins was confirmed in the Western blot.
- Similarly, for the MALDI-TOF analysis, a sufficient number of unique peptides (including N-terminal peptides) were mapped to confirm DMO and DMO+27 identity. In addition, a separate N-terminal sequencing analysis concurred with the results of the MALDI-TOF analysis; the SDS-PAGE analysis confirmed that the calculated molecular weights of the two protein monomers were as expected; and the immunoreactivity was confirmed.
- For the glycosylation analysis, there was no positive detection using the Glycoprotein Detection Kit. In addition, the occurrence of even one sugar residue on the peptide chain would be likely to increase the apparent molecular weight, because of impaired SDS binding, and be detectable in SDS-PAGE. No such detection in SDS-PAGE was noted.

  In any case, information on the sensitivity of the commercially available detection kit used for the analysis is available on the manufacturer's website.

x. The published crystallography of DMO[6] was based on DMO isolated from E. coli. *No evidence has been provided that the crystal structure of MON87708-derived DMO is the same as the* E. coli*-derived DMO.*

The protein used in the protein characterisation studies was sourced from MON87708. A partial exception to this was the enzyme specificity study where the major experiment was done using DMO obtained from *E. coli* but where a small follow-up experiment used DMO isolated from MON87708 for the express purpose of confirming that the amino acid differences between *E. coli*- and plant-derived DMO did not affect specificity.

A consideration of the crystallographic structure of *E. coli*-derived DMO was of no relevance to the safety assessment since other indicators (immunoreactivity, activity, substrate specificity, digestibility) raised no safety concerns with the DMO protein from MON87708.

xi. In the analysis for the presence of vector backbone, the Applicant has failed to account for potential inserts that are only partial or have rearrangements.

FSANZ is satisfied that the four probes used by the Applicant were sufficient to test for any significant hybridisation with backbone sequences.

[6] D'Ordine et al (2009). Journal of Molecular Biology 392: 481 – 497.

xiii. The Applicant has not analysed for evidence of disruption of endogenous ORFs or regulatory sequences. There is no survey of RNAs that may have been deleted by e.g. transcriptome sequencing.

The *Application Handbook* does not stipulate the inclusion of this information. FSANZ considers that such information is not required to evaluate safety where the weight-of-evidence does not raise safety concerns, as was the case for soybean MON87708.

Transcriptome techniques are not yet fully developed and validated and have certain limitations that preclude their routine use for safety assessments of GM foods.

In particular, their usefulness for the identification of unintended effects in GM crops depends largely on documented information about natural variations in gene expression levels in conventional crop plants, which is still lacking. Without this baseline information, it would be difficult to draw any meaningful conclusions with regard to safety.

3.3 Risk communication

FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was notified via 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 A1063 is available on the website at
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1063food5198.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 MON87708 in Australia and New Zealand was approved on the basis of the 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 MON87708.
- Food derived from soybean line MON87708 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 MON87708 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 draft variation; or (2) approval of the draft variation to permit food derived from soybean line MON87708 in Standard 1.5.2. Following analysis of the potential costs and benefits of each option on affected parties (consumers, the food industry and government), Option 2, approval of a variation, was the preferred option. Under Option 2, the potential benefits to all sectors outweigh the costs associated with the approval.

- 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

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 impact 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 MON87708.

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 MON87708 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 MON87708 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 MON87708 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 MON87708 would be required to be labelled.

As food from soybean line MON87708 has been found to be as safe as food from conventional cultivars of soybean, rejecting the variation would offer little benefit to consumers, as approval of soybean line MON87708 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 soybean line MON87708 from those containing approved soybean lines which would be likely to increase the costs of imported soybean-derived foods. Also, to reject 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.

4.1.1.2 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

Monsanto submitted a food and feed safety and nutritional assessment summary for MON87708 to the United States Food and Drug Administration (FDA) in November 2010. A completed consultation was notified by the FDA on 18 October 2011.

Monsanto also requested a Determination of Nonregulated Status for MON87708, including all progeny derived from crosses between MON 87708 and other soybean, from the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture in July 2010. Applications have also been submitted to the Canadian Food Inspection Agency and Health Canada in November 2010, the European Food Safety Authority in January 2011, Korean Food and Drug Administration for food use in February 2011, and Rural Development Administration for feed use in February 2011, and Japan's Ministry of Health, Labour, and Welfare for food use in March 2011.

The Applicant states that submissions are likely to be made to a number of additional governmental regulatory agencies including the Ministry of Agriculture, People's Republic of China; Japan's Ministry of Agriculture, Forestry, and Fisheries; and the Intersectoral Commission for Biosafety of Genetically Modified Organisms, Mexico.

It is the Applicant's intention that soybean line MON87708 be commercially cultivated primarily in major soybean-growing countries. FSANZ understands there is currently no intention to apply for approval to cultivate this variety in either Australia or New Zealand.

The cultivation of any GM crop 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 soybean line MON87708 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 MON87708 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 MON87708 would be required 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) 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 soybean line MON87708.

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

  For GM foods, there are no relevant guidelines.

4.3 Implementation

The variation would 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.

Liu, K.S., Orthoefer, F. and Thompson, K. (1995) The case for food-grade soybean varieties. *INFORM* 6(5):593-599.

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 A1063 – Food derived from Herbicide-tolerant Soybean MON87708) 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

[Signature to be inserted]

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

1 Name

This instrument is the *Food Standards (Application A1063 – Food derived from Herbicide-tolerant Soybean MON87708) 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

This variation commences **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 MON87708	

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 A1063 which seeks permission for the sale and use of food derived from herbicide-tolerant soybean line MON87708. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation[7], 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 MON87708 is not currently permitted for sale or use in food. Therefore, FSANZ has approved a variation to Standard 1.5.2 to include food derived from soybean line MON87708 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 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 18 October 2011 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.

[7] 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

The item adds food derived from soybean line MON87708 into the Schedule to Standard 1.5.2.