

2 June 2015
[10–15]

Approval Report – Application A1097

Food derived from Herbicide-tolerant and Insect-protected Corn Line MON87411

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Monsanto Australia Ltd seeking permission for food derived from corn line MON87411, which is genetically modified to provide tolerance to the herbicide glyphosate and protection against corn rootworm, in particular western corn rootworm.

On 16 December 2014, FSANZ sought submissions on a draft variation to Standard 1.5.2 and published an associated report. FSANZ received 23 submissions.

FSANZ approved the draft variation to the Standard on 20 May 2015. The Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 26 May 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 document

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/A1097GMCornLineMON87411.aspx>

SD1 Safety Assessment Report (at Approval)

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Monsanto Australia Ltd on 15 July 2014. 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 a genetically modified (GM) corn line, MON87411, that is tolerant to the herbicide glyphosate and protected against western corn rootworm.

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 herbicide-tolerant and insect-protected corn line MON87411 (also referred to as MON87411) is provided in Supporting Document (SD) 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 MON87411 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

The FSANZ Board has approved draft variations to the Schedule of Standard 1.5.2 of the current Code and to Schedule 26 of the revised Code that include a reference in each to food derived from herbicide-tolerant and insect-protected corn line MON87411.

1 Introduction

1.1 The Applicant

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

1.2 The Application

Application A1097 was submitted by Monsanto Australia Ltd on 15 July 2014. It sought approval for food derived from herbicide-tolerant and insect-protected corn line MON87411 (also referred to as MON87411) under Standard 1.5.2 – Food produced using Gene Technology.

MON87411 has been modified such that it is both tolerant to the herbicide glyphosate and protected against corn rootworm, particularly western corn rootworm.

Tolerance to glyphosate is achieved through expression of the enzyme 5-enolpyruvyl-3-shikimatephosphate synthase (CP4 EPSPS) encoded by the *cp4epsps* gene derived from the common soil bacterium *Agrobacterium* sp. strain CP4. The CP4 EPSPS protein in corn line MON87411 is identical to the CP4 EPSPS protein present in 14 other lines that have been developed by Monsanto and approved by FSANZ.

Protection against corn rootworm occurs via two genetic modifications:

- The expression of a *cry3Bb1* gene that produces a modified *Bacillus thuringiensis* (subsp. *kumamotoensis*) Cry3Bb1 protein to protect against larval feeding. The safety of the Cry3Bb1 protein has been previously assessed by FSANZ in two other approvals involving corn rootworm-protection.
- The expression of a suppression cassette containing an inverted repeat sequence from the western corn rootworm (*Diabrotica virgifera virgifera*) *Snf7* gene. This sequence is expressed in the tissue of corn line MON87411 and results in the formation of a double-stranded RNA (dsRNA) transcript containing a fragment of the *Snf7* gene. When plant tissue is ingested by corn rootworm, the plant-produced dsRNA is recognised by the corn rootworm RNA interference (RNAi) machinery and results in down-regulation of the endogenous *Snf7* gene and subsequent death of the insect.

According to the Applicant, MON87411 will not be offered for commercial use as a stand-alone product, but will be combined, through traditional breeding, with other approved GM corn lines (a process known as ‘stacking’).

1.3 The current Standard

Standard 1.5.2 sets out the permission and conditions for the sale and use of food produced using gene technology (a GM food).

Pre-market approval is necessary before a GM food may enter the Australian and New Zealand food supply. Approval of such foods under Standard 1.5.2 is contingent on completion of a comprehensive pre-market safety assessment. Foods that have been assessed and approved are listed in the Schedule to the Standard.

Standard 1.5.2 contains specific labelling provisions for approved GM foods. Such foods 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 may also specify additional labelling about the nature of the altered characteristics.

Standard 1.5.2 is replicated in the revised Code. The relevant Schedule in that version of the Code is Schedule 26.

1.4 Reasons for accepting the 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 to Standard 1.5.2 of the current Code, as proposed following assessment, was approved without change. As a consequence, a draft variation to Schedule 26 of the revised Code was also approved.

The approved draft variation to Standard 1.5.2 of the current Code takes effect on gazettal.

The approved draft variation to Schedule 26 of the revised Code takes effect on 1 March 2016, which is the date on which the revised Code comes into effect.

The approved draft variations and related explanatory statements are at Attachments A and 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

A total of 23 submissions were received. Of these, some raised issues that are outside the scope of FSANZ's regulatory area e.g. public perception of GM food; opinions about biotechnology developers; enforcement of Standards in the Code; maintaining a GM-free trade status and environmental issues. In the latter case, issues to do with 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 11 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"> • Auckland GE Free Coalition (AGEFC) • Tania Condren • Michelle Denise • FOODwatch • Wambui Gikenye • GM Free Australia Alliance (GMFAA) • Fiona Guyan • Hugh Halliday • Susie Lees • Submitter1 (name redacted) • Rebekah Summer & Mark Halcroft • Karen Tough • Physicians & Scientists for Global Responsibility (PSGR) 	<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; however it 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/reviewofgeneticallym4394.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/Pages/default.aspx).</p>
<p>Lack of consideration of long term feeding studies in the safety assessment</p>	<ul style="list-style-type: none"> • FOODwatch • GMFAA • Submitter1 (name withheld on request) 	<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 for MON87411 showed that grain from MON87411 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 MON87411, 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>

Issue	Raised by	FSANZ response
<p>FSANZ, in carrying out its assessment of the Application, has compromised sound scientific process by favouring trade outcomes.</p>	<ul style="list-style-type: none"> • AGEFC • Susie Lees 	<p>The primary objective of FSANZ in developing or varying a food regulatory measure, (see s 18 of the FSANZ Act), is the protection of public health and safety. Accordingly, the safety assessment forms the central component in considering an application. If the safety assessment identifies a safety concern, it is unlikely that the food would be considered for approval. If, on the other hand, the safety assessment does not identify any safety concerns, then a number of other statutory obligations, including Australia's and New Zealand's ability to meet their obligations under the WTO, must be considered in relation to the approval.</p>
<p>Concern that the FSANZ public submission process is a sham because FSANZ takes no notice of submissions</p>	<ul style="list-style-type: none"> • Submitter1 	<p>Every submission on each application received by FSANZ is considered by the FSANZ Board. All submissions are addressed, as evidenced from Section 2.1 of this Report. As stated in Section 2.4 of this report, all comments are valued and contribute to the rigour of the safety assessment.</p>
<p>Concern that the FSANZ Board has a pecuniary interest in RNAi technology and this represents a conflict of interest</p>	<ul style="list-style-type: none"> • Submitter 1 	<p>FSANZ Board members are subject to the requirements of the <i>Public Governance, Performance And Accountability Act 2013</i> and the FSANZ Act. When a new Board member is appointed, they are required to complete various declaration forms concerning pecuniary, academic and other interests that could give rise to a conflict involving FSANZ's business and operations. These declaration forms are tabled at Board meetings and amended from time to time as members' interests change. Additionally, at each Board meeting, members must identify agenda items for which they may have a conflict of interest (real or perceived). Where the Board considers that such a conflict exists, the Board member is either required to be absent during consideration of the item in question or to not vote.</p> <p>The Board receives advice on conflict of issues.</p>
<p>Bt crops have been linked to health and environmental issues</p>	<ul style="list-style-type: none"> • GMFAA • MADGE 	<p>There has been widespread consideration about the safety of GM crops modified to contain Cry genes (see e.g. Mendelsohn et al. 2003; Hammond and Koch 2012) and the conclusion reached through assessment of the data available is that Bt crops do not pose a safety concern.</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 maximum residue limits (MRLs) when <i>Bt</i> is used as an insecticide.</p>

Issue	Raised by	FSANZ response
<p>Concern with the use of herbicides in general and glyphosate in particular</p>	<ul style="list-style-type: none"> • Tania Condren • Michelle Denise • GMFAA • Hugh Halliday • Susie Lees • Mothers are Demystifying Genetic Engineering (MADGE) • Submitter1 • PSGR • Brian Sandle • Rebekah Summer & Mark Halcroft 	<p>The use of agricultural and veterinary chemicals is subject to strict government regulation in most trading countries. In Australia and New Zealand, residues of agricultural and veterinary chemicals are prohibited in food (both GM and non-GM) unless they comply with specific limits referred to as MRLs. FSANZ and the Australian Pesticides and Veterinary Medicines Authority (APVMA) have shared responsibilities in relation to MRLs for food. The setting of MRLs ensures that residues of agricultural and veterinary chemicals are kept as low as possible and consistent with the approved use of chemical products to control pests and diseases of plants and animals. For further details see the FSANZ website at http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets/chemicalsinfoodmaxim5429.cfm.</p> <p>In undertaking a risk-based assessment to support an MRL, the key issue is whether, in the context of the Australian/New Zealand diet, the consumption of chemical residues in a food remains below the health-based guidance values. Herbicide MRLs themselves are not food safety limits. They specify the amount of permitted residue remaining in a harvested crop after the minimum amount of herbicide has been applied to control weed growth. Exceeding an established MRL can occur but it does not necessarily make a food unsafe because the level that is set (and regularly reviewed to take into account changing usage) is designed to ensure the minimum residue level, not the maximum permissible before there is a health and safety concern.</p> <p>The following points about glyphosate are relevant:</p> <ul style="list-style-type: none"> • The MRL pertaining to glyphosate is given in Standard 1.4.2 (http://www.comlaw.gov.au/Details/F2014C01358/Html/Volume_2) and the Applicant has indicated that no change to this MRL is being sought as a result of the intended herbicide use on MON87411. • Glyphosate is a non-selective systemic herbicide with uses on both conventional and GM crops as well as in forestry, industrial weed control, lawn, garden, and aquatic environments (Henderson et al. 2010). • Glyphosate MRLs for a variety of plant-derived food commodities have been adopted by Codex (http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp), NZ (http://www.foodsafety.govt.nz/elibrary/industry/nz-mrl-agricultural-compounds-food-standards-07-2014.pdf) and Australia (http://www.comlaw.gov.au/Details/F2013C00638). • The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) concluded (FAO 2005) that “the long-term intake of residues of glyphosate... from uses that have been considered by the JMPR is unlikely to present a public health concern”. • A recent summary report put out by the WHO International Agency for Research on Cancer (IARC) (Guyton et al. 2015) has classified glyphosate as a Group 2A carcinogen (probably carcinogenic to humans). This conclusion is in stark contrast to the ‘non-carcinogenic’ classification given to the herbicide by a number of national and international expert committees. Unfortunately, since the full monograph of the IARC will not be published for some time FSANZ is unable to comment on the reasons why IARC’s conclusion differs so markedly from the WHO specialist committee on pesticides (ie. JMPR).

Issue	Raised by	FSANZ response
<p>Current GM labelling is inadequate</p>	<ul style="list-style-type: none"> • CHOICE • FOODwatch • GMFAA • MADGE • Submitter1 	<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 recommendations contained in the Final Report on an independent Review of Food Labelling Law and Policy. 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 on the Food Labelling Review website at: http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/content/labelling-logic</p>
<p>Any food plant with novel engineered DNA is not "equivalent" to a conventional food plant'.</p>	<ul style="list-style-type: none"> • PSGR 	<p>The main purpose of a GM food safety assessment is to identify new or altered hazards associated with the food as a result of the genetic modification. If a new or altered hazard, nutritional or other food safety concern is identified, further assessment is done to determine its relevance to human health. The first step in this assessment is to undertake a comparison between the GM food and a conventional counterpart food having an acceptable standard of safety to determine if there are any differences. In the second part of the assessment, any identified differences are subject to further scrutiny to determine if they raise potential safety or nutritional concerns. The expression of a novel protein, as a result of the insertion of novel DNA, constitutes a relevant difference that requires further scrutiny. If it is determined that the identified differences do not raise any safety or nutritional concerns then it can be concluded that the GM food is comparable to the conventional counterpart food in terms of its safety for human consumption. This does not mean there are no differences, only that the differences do not impact on the safety of the food.</p>

Issue	Raised by	FSANZ response
<p>The safety of ingesting transgenes</p> <p>Horizontal gene transfer</p>	<ul style="list-style-type: none"> • PSGR • Submitter1 	<p>DNA is a natural component of the human diet, being present to varying degrees in many plant- and animal- derived foods, especially those that have undergone minimal processing. There is no difference in terms of risk between small fragments of 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>Lack of post-market monitoring of GM foods once they are approved</p>	<ul style="list-style-type: none"> • AGEFC • Susie Lees 	<p>In the context of a GM food, it has been recognised internationally that the use of pre-market safety assessment provides assurance that a GM food is comparable to its conventional counterpart in relation to health risks and benefits, therefore the likelihood of identifying long-term effects specifically attributable to GM foods would be very low (WHO 2000). Moreover, the practicality of using post-market monitoring (PMM) to assess the long-term human health impacts of consuming GM foods has not been established.</p> <p>Many chronic health problems have complex causes and it is unlikely that observational epidemiological studies could identify such effects specifically related to GM foods. The same also applies to the identification of potential long-term beneficial health effects.</p> <p>In general, therefore, FSANZ does not consider PMM to be a practical, enforceable or effective risk management option. This is particularly the case where passive monitoring or general health surveillance, which does not address a specific hypothesis, is proposed.</p> <p>Nevertheless, it is recognised that PMM may be an appropriate risk management measure in certain circumstances, e.g. where a GM food has been developed specifically to produce a nutritional effect in the population and it may therefore be desirable to confirm assumptions made during the risk assessment. FSANZ decides the need for PMM on a case-by-case basis, taking into account the unique characteristics of the GM food and the feasibility of undertaking such a study.</p>

2.1.2 Issues raised specific to the Application

2.1.2.1 *The studies used to show the safety of MON87411*

One submitter was concerned that the safety assessment for A1097 relies on published information that is not specific to MON87411 to support the conclusion that food derived from MON87411 is safe.

FSANZ's safety assessment relies largely on relevant safety data generated by the Applicant complemented, where appropriate, by information from the scientific literature. The safety data generated by the Applicant and supplied with the Application is specific to the particular food in question.

For an Application to be accepted, it must comply with the data requirements set out in the *Application Handbook* (FSANZ 2013a). The Applicant for A1097 met all of the data requirements stipulated in the *Application Handbook* (FSANZ 2013a) for the safety assessment of a GM food and, upon assessment of these data, FSANZ is satisfied that sufficient evidence has been provided to demonstrate the safety of food derived from MON87411.

In addition to these studies, FSANZ also relies on general scientific information in the published literature to inform its conclusions, and any assumptions on which these may be based.

2.1.2.2 *Inadequate assessment of the dsRNA in MON87411*

Some submitters (Centre for Integrated Research in Biosafety – INBI, GMFAA and MADGE) claim that FSANZ has not undertaken an adequate safety assessment for evaluating the DvSnf7 dsRNA and that a different approach should be used for traits involving RNAi.

The INBI submission claims this different approach should be taken because:

- Other regulators disagree with FSANZ – INBI cites only the US Environmental Protection Agency (EPA)
- FSANZ has not adequately considered non-ingestion pathways for dietary dsRNA

All three submissions claim that FSANZ ignores or dismisses peer-reviewed science

These points are addressed as follows:

The EPA disagrees with FSANZ

In 2013, FSANZ publicly stated its position in relation to RNAi (FSANZ 2013b) when it responded to a paper by Heinemann et al (2013)² which claimed that small dsRNAs produced in GM plants as a result of the use of RNAi technology can create unique risks to human health and safety and that these risks are not being adequately addressed by regulators. FSANZ concluded that ingested small dsRNAs are generally safe for human consumption and that the current food safety assessment approach was adequate to address any potential risks posed by the use of RNAi in plants.

INBI claims the EPA has since concluded that existing risk assessment frameworks are not sufficient to evaluate dsRNA for safety.

In 2013, the EPA (US EPA 2013) submitted a white paper on RNAi technology to the Federal Insecticide, Fungicide & Rodenticide Act (FIFRA) Science Advisory Panel. The paper sought to provide details of what is already known about RNAi and to consult with the FIFRA panel on scientific issues that might be unique to RNAi and how these could fit under the existing risk assessment framework.

In turn, the FIFRA panel (FIFRA SAP 2014) addressed seven questions, three of which were specific to human health considerations and four of which were specific to environmental considerations.

² Heinemann JA, Agapito-Tengfen SZ, Carman J (2013) A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments. *Environment International* 55:43–55

While the FIFRA panel recommended that additional work could be done to address particular knowledge gaps in relation to human health considerations, they also concluded that pest control products using RNAi technology are not likely to result in adverse effects to humans through ingestion exposures. They noted that dietary RNA is extensively degraded in the mammalian digestive system by a combination of ribonucleases (RNases) and acids that are likely to ensure all structural forms of RNA are degraded throughout the digestive process. They also stated there is no convincing evidence that ingested dsRNA is absorbed from the mammalian gut in a form that causes physiologically relevant adverse effects. This conclusion is consistent with that reached by FSANZ (FSANZ 2013b) and reiterated in Section 4.2.3 of the safety assessment for this Application.

In relation to the adequacy of existing risk assessment frameworks, the FIFRA panel's conclusions regarding this were confined to the environmental risk assessment, where they indicated that additional information should be collected to address uncertainties in the environmental fate and ecological risk assessments. This conclusion is not directly relevant to the food safety assessment.

The US EPA has not yet responded to the FIFRA panel's recommendations, therefore there is no official EPA position.

In relation to regulators other than the EPA, the US Food and Drug Administration has completed its assessment of MON87411 and has stated it has no further questions regarding food and feed safety at this time³.

FSANZ has not adequately considered non-ingestion pathways in humans for dsRNA

In its submission, INBI refers to the FIFRA panel's report which recommends that other exposure pathways be tested. A non-ingestion pathway, e.g. inhalation or dermal contact, for substances that are, or are contained in, food is a very minor primary exposure route. Coupled with this is the inherent capability of the lungs and the skin to successfully exclude large molecules from secondary exposure sites within the body, a property that is shared by the gastro-intestinal tract (discussed in Section 4.2.3 of the SD1). For example, physiological barriers in the lungs such as mucociliary clearance actions and phagocytosis by macrophages can effectively remove small RNAs, and any that escape are likely to enter systemic circulation and be renally excreted in a short time (Moschos et al. 2011). Even specific targeting of lung cells for therapeutic treatment using RNAi is considered to require sophisticated delivery carriers, chemical modification, and modified RNAi platforms (Fujita et al. 2015).

In terms of hazard, data provided in the SD1 indicate that neither dsRNA nor small RNAs represent a concern. Therefore, with an exposure level much less than that associated with ingestion (which itself results in low exposure) and no significant hazard identified, there is no scientific justification in a food safety assessment for considering exposure pathways with even lower risk than ingestion.

FSANZ ignores or dismisses peer-reviewed science

The GMFAA, INBI and MADGE submissions refer to two papers that were published in 2014 which they claim provide new evidence that ingested small RNAs can exert biological effects in humans. These are:

³ <http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/UCM427607>

- A paper by Baier et al⁴ (2014) which reported that following oral administration of cow's milk to healthy human volunteers there was a transient increase in two miRNAs, identical to those found in humans, in the participant's blood and that this was due to uptake of the cow miRNAs following ingestion. The authors also reported these cow miRNAs were able to alter gene expression in human cell cultures.
- A paper by Lukasik & Zielenkiewicz (2014)⁵ which reported the identification of plant miRNAs in mammalian breast milk exosomes using bioinformatic analysis of publicly available, raw data from small RNA high-throughput sequencing studies. The authors also used bioinformatic analysis to predict potential human gene targets for the five most abundant plant miRNAs and identified 1,282 unique human mRNAs.

The proposal that ingested small RNAs can exert biological effects in humans is both controversial and highly speculative and has been previously discussed by FSANZ (FSANZ 2013b). In relation to actual uptake, a number of conflicting pieces of evidence exist and it therefore continues to remain an area of uncertainty. While the number of negative studies published so far suggests that uptake of ingested small RNAs is not a widespread phenomenon in mammals including humans, it cannot be completely ruled out. However, following uptake, there are numerous conditions that need to be met and biological barriers to be overcome before an exogenous small RNA could exert a biological effect, including a potentially adverse effect. The overwhelming evidence to date suggests this is unlikely and certainly no more likely for the small RNAs and dsRNAs produced in GM plants compared to the other small RNAs that are naturally abundant in the human diet.

There is no evidence of harm to human health from ingested small RNAs and dsRNAs from either GM foods or non-GM foods.

FSANZ will continue to monitor the scientific literature for any developments in relation to RNAi technology which may be relevant to the GM food safety assessment.

A recent study by Petrick et al (2015)⁶ failed to demonstrate that ingested dsRNA has no effect on mammals. The INBI submission outlines a number of flaws they perceive with the study.

Petrick et al (2015) undertook a mouse toxicity study to test the biological barriers to the uptake and activity of a synthetic dsRNA and synthetic siRNAs designed specifically to target the mouse orthologue of the vacuolar ATPase gene (an established target for the control of corn rootworm). The ability of the siRNAs to suppress the activity of the target mouse gene was confirmed in experiments using mouse kidney cells. Groups of mice were gavaged daily with either the siRNAs or the dsRNA at doses up to 48 mg/kg bodyweight/day and 64 mg/kg bodyweight/day, respectively, for 28 days. These doses were considered to be at levels several orders of magnitude higher than would occur in products derived from GM crops currently under development. The authors reported there were no treatment-related effects on body weight, food consumption, clinical observations, clinical chemistry, haematology, gross pathology, or histopathology endpoints. There was also no treatment related suppression of the vacuolar ATPase gene in selected gastrointestinal tract and systemic tissues.

⁴ Baier SR, Nguyen C, Xie F, Wood JR, Zemleni J (2014) MicroRNAs are absorbed in biologically meaningful amounts from nutritionally relevant doses of cow milk and affect gene expression in peripheral blood mononuclear cells, HEK-293 kidney cell cultures, and mouse livers. *The Journal of Nutrition* 144:1495–1500

⁵ Lukasik A, Zielenkiewicz P (2014) *In silico* identification of plant miRNAs in mammalian breast milk exosomes - a small step forward? *PLoS ONE* (open access) 9(6):e99963.

⁶ Petrick JS, Moore WM, Heydens WF, Koch MS, Sherman JH, Lemke SL (2015) A 28-day oral toxicity evaluation of small interfering RNAs and a long double-stranded RNA targeting vacuolar ATPase in mice. *Regulatory Toxicology and Pharmacology* 71:8–23

The authors claim the results of this study indicate that orally ingested dsRNAs, even those designed to deliberately target a gene in a test mammalian species, do not produce adverse health effects even at extremely high dose levels.

This study does not have any direct relevance to the safety of food derived from MON87411 and was not relied upon by FSANZ for the food safety assessment. However, FSANZ considers the results of this study further contribute to the evidence base which demonstrates that ingested dsRNAs and small RNAs are generally safe for human consumption.

2.1.2.3 Anomalous result in the Acute Oral Toxicity Study

Brian Sandle notes that the results of an acute oral toxicity study (MSL-18711) submitted in support of the Application show there was a statistically significant body weight increase in both male and female mice gavaged with the Cry3Bb1 protein compared with the control mice. He was concerned that this weight increase could be related to a steroid-like effect of xeno-oestrogens or more highly expressed natural phyto-oestrogens and therefore, on these grounds, there should not be an approval of food from MON87411. While statistically significant differences were found in the studies, in biological terms the differences were small. The standard deviations for the individual body weight changes were very large for both the test and control groups and importantly, there was no consistent growth rate, or loss of body weight in either group.

If this was a relevant steroidal/estrogenic effect, the mean group bodyweight differences would be expected to be much more marked and there would also need to be much more consistency within groups. Differences that are statistically significant but biologically insignificant are common in animal studies, especially rodent studies.

2.2 Safety assessment

The safety assessment of MON87411, as amended following the Call for Submissions, 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 corn 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 MON87411 was restricted to human food safety and nutritional issues. This assessment therefore does not address any risks to human health more broadly, 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.

The Applicant for A1097 met all of the data requirements stipulated in the *Application Handbook* (FSANZ 2013a) for the safety assessment of GM food and, after assessing these data, FSANZ is satisfied that sufficient evidence has been provided to demonstrate the safety of the food.

FSANZ sought comments on the SD1, particularly the RNAi aspects, from two academic experts. The comments from both reviewers were favourable and neither disagreed with FSANZ's conclusion on the safety of MON87411. Some minor changes were made to the SD1 in response to suggestions from one of the reviewers.

Based on the scientific data provided in the present Application, and other available information, food derived from MON87411 is considered to be as safe for human consumption as food derived from conventional corn cultivars.

2.3 Risk management

2.3.1 Labelling

In accordance with Standard 1.5.2, food derived from MON87411 would be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein; or if it has altered characteristics. Food from MON87411 does not have altered characteristics.

MON87411 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, are unlikely to contain any novel protein or novel 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 MON87411 would be unlikely to require labelling.

MON87411 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 MON87411 event are also likely to 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-Committee⁷ to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including GM applications.

The EAG indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA is 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 DAS-81910-7 to satisfy the requirement for detection methodology in the FSANZ *Application Handbook* (FSANZ 2011).

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 16 December 2014 and 10 February 2015.

⁷ Now known as the Implementation Subcommittee for Food Regulation

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 23 submissions were received, of which 20 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 A1097, 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 A1097, outweigh the costs to the community, Government or industry.

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 the assumption that MON87411 (and any lines containing the MON87411 event) will be approved for growing in other countries (see section 2.5.1.4 below).

Consumers: Broader availability of imported corn products as, if MON87411 is approved for commercial growing, there would be no restriction on imported foods containing this line.

For those MON87411 products containing novel DNA or novel protein, appropriate labelling would allow consumers wishing to avoid these products to do so.

If MON87411 is approved for commercial growing in overseas countries, it can be used in the manufacture of products using co-mingled corn.

This means that there would be no cost involved in having to exclude MON87411 from co-mingling and hence that there would be no consequential need to increase the prices of imported foods that are manufactured using comingled corn products.

Government: Benefit that if MON87411 was detected in food imports, approval would ensure compliance of those products with the Code. This would ensure no potential for trade disruption on regulatory grounds.

Approval of MON87411 would ensure no conflict with WTO responsibilities if the line is approved for commercial growing in overseas countries.

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 MON87411 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 food ingredients derived from MON87411 would be required to be labelled if they contain novel DNA or novel protein.

The segregation of raw agricultural commodities of MON87411, 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.

As food from MON87411 has been found to be as safe as food from conventional cultivars of corn, not preparing a draft variation would offer little benefit to consumers, as approval of MON87411 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 MON87411 from those containing approved corn lines which would be likely to increase the costs of imported corn-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 varied as a result of Application A1097.

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 MON87411 to a number of other countries, as listed in Table 2. Of these, the application to the US Food & Drug Administration was noted as a completed Biotechnology consultation as of 17 October 2014. No decision has yet been made on the other applications.

Table 2: List of countries to whom applications for regulatory approval of MON87411 have been submitted

Country	Agency	Type of approval sought	Status
USA	Department of Agriculture (APHIS)	environment	Being assessed
	Food & Drug Administration	food/feed	Finalised 17/10/2014
Canada	Canadian Food Inspection Agency	feed	Being assessed
	Health Canada	food	Being assessed
Japan	Ministry of Health, Labour and Welfare	food	Being assessed
	MAFF	feed	Being assessed
	MAFF/MOE	environment	Being assessed
Korea	Ministry of Food and Drug Safety	food	Being assessed
	Rural Development Administration	feed	Being assessed
Argentina	CONABIA	food	Being assessed
	SENASA	feed	Being assessed
Taiwan	Taiwan Food and Drug Administration	food	Being assessed
European Union	European Food Safety Authority	food	Being assessed

It is the Applicant's intention to submit applications for food/feed regulatory approvals to other countries such as China that may import corn food/feed products from countries where lines containing the MON87411 event will be grown.

It is the Applicant's intention that lines containing the MON87411 event be commercially cultivated predominantly in North America. 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 MON87411 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 MON87411 is considered as safe and wholesome as food derived from other commercial corn 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 MON87411 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 General Principles for the Risk Analysis of Foods derived from Biotechnology (Codex 2004). Based on these principles, the risk analysis undertaken for MON87411 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 Applicants, 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. MON87411 is a new food crop designed to provide growers with an alternative pest management strategy.

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

If MON87411 is approved for commercial growing in other countries, it is appropriate that Australian and New Zealand importers have access to food products derived from the line.

- **any written policy guidelines formulated by the Ministerial Council⁸**

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

⁸ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

3 Transitional arrangements

3.1 Transitional arrangements for Code Revision

FSANZ has completed a review of the Code undertaken under Proposal P1025⁹ in order to improve its clarity and legal efficacy. Following approval of the revision and Ministerial consideration, the new Code will commence on 1 March 2016 (following gazettal and registration on the Federal Register of Legislative Instruments). The current Code will also be repealed on that date.

The approved variation at Attachment B varies the revised Code. It will amend the revised Code on commencement to ensure that the revised Code is consistent with the current Code as amended by the variation at Attachment A.

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⁹ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

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Attachments

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

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



Food Standards (Application A1097 – Food derived from Herbicide-tolerant and Insect-protected Corn Line MON87411) 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 [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**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1097 – Food derived from Herbicide-tolerant and Insect-protected Corn Line MON87411) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

SCHEDULE

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

“

	2.22	Food derived from herbicide-tolerant and insect-protected corn line MON87411	
--	------	--	--

”

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 A1097 which seeks permission for the sale and use of food derived from herbicide-tolerant and insect-protected corn line MON87411 (MON87411). The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation¹⁰, 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 herbicide-tolerant and insect-protected corn line MON87411 into the Schedule to Standard 1.5.2 in order to permit the sale, or use in food, of food derived from that corn 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 A1097 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 16 December 2014 for an eight-week consultation period.

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.

¹⁰ convening as the Australia and New Zealand Food Regulation Ministerial Council

6. Variation

Item [1] of the Variation inserts Item 2.22 into the Schedule to Standard 1.5.2. Item 2.22 refers to food derived from herbicide-tolerant and insect-protected corn line MON87411.

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



Food Standards Australia New Zealand Code – Transitional Variation 2015 (Application A1097 – Food derived from Herbicide-tolerant and Insect-protected Corn Line MON87411)

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 [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**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name of instrument

This instrument is the *Food Standards Australia New Zealand Code – Transitional Variation 2015 (Application A1097 – Food derived from Herbicide-tolerant and Insect-protected Corn Line MON87411)*

2 Commencement

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

3 Variation of Schedule 26

Schedule 1 varies Schedule 26 of the *Australia New Zealand Food Standards Code – Food produced using gene technology*.

Schedule 1 Variation of Schedule 26

[1] Table to section S26—3

Under the entry for “Corn”, insert after item (u)

“

(v) herbicide-tolerant and insect-protected corn line MON87411”

”

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 A1097 which seeks permission for the sale and use of food derived from herbicide-tolerant and insect-protected corn line MON87411 (MON87411). The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation¹¹, 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 herbicide-tolerant and insect-protected corn line MON87411 into the Schedule 26 of the Code in order to permit the sale, or use in food, of food derived from that corn 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 A1097 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 16 December 2014 for an eight-week consultation period.

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.

¹¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

6. Variation

Item [1] of the Variation inserts Item 2(v) into the Schedule 26 of the Code. Item 2(v) refers to food derived from herbicide-tolerant and insect-protected corn line MON87411.