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Approval report – Application A1192

Food derived from herbicide-tolerant corn line MON87429

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Monsanto Australia Proprietary Limited seeking approval for food derived from a herbicide-tolerant corn line MON87429. Corn line MON87429 has been genetically modified to tolerate glufosinate, dicamba, 2,4-D and the aryloxyphenoxypropionate group of herbicides (known as FOPs). MON87429 also has tissue-specific herbicide tolerance to glyphosate.

On 26 March 2020, FSANZ sought [submissions](#) on a draft variation to Schedule 26 and published an associated report. FSANZ received 33 submissions.

FSANZ approved the draft variation on 16 September 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 24 September 2020.

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

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Supporting document

The [following document](#)¹ which informed the assessment of this Application is available on the FSANZ website:

SD1 Safety Assessment Report

¹ <https://www.foodstandards.gov.au/code/applications/Pages/A1192.aspx>

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Monsanto Australia Proprietary Limited requesting a variation to Schedule 26 in the Australia New Zealand Food Standards Code (the Code) to include food derived from a new genetically modified (GM) corn (*Zea mays*) line, MON87429. This corn line has been genetically modified to tolerate glufosinate, dicamba, 2,4-D and the aryloxyphenoxypropionate group of herbicides (known as FOPs). MON87429 also has tissue-specific herbicide tolerance to glyphosate.

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in section 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 MON87429 is in Supporting Document 1 (SD1). No potential public health and safety concerns have been identified. Based on the data provided and other information, food derived from MON87429 is considered to be as safe for human consumption as food derived from conventional (non-GM) corn cultivars. In addition, current labelling requirements for genetically modified food will apply to foods for sale that consist of, or have as an ingredient, food that is a genetically modified food.

The FSANZ Board has approved the draft variation to Schedule 26 of the Code that inserts a reference into that Schedule to food derived from corn line MON87429. The effect of the variation is to permit the use or sale of food derived from that corn line in accordance with Standard 1.5.2 of the Code.

1 Introduction

1.1 The Applicant

Monsanto Australia Proprietary Limited is a technology provider to a number of sectors including the agriculture sector.

1.2 The Application

Application A1192 was submitted on 31 October 2019. It seeks a variation to Schedule 26 in the Australia New Zealand Food Standards Code (the Code) to include food from a new genetically modified (GM) corn (*Zea mays*) line, MON87429. This corn line has been genetically modified to tolerate the following herbicides: glufosinate, dicamba, 2,4-dichlorophenoxyacetic acid (2,4-D) and the aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase inhibitors (known as FOPs herbicides). MON87429 has also been genetically modified to provide tissue-specific tolerance to glyphosate to facilitate hybrid seed production.

This tolerance is achieved through expression of a:

- *pat* gene from *Streptomyces viridochromogenes*, which encodes a phosphinothricin-N-acetyltransferase (PAT) protein and provides tolerance to glufosinate herbicide;
- *dmo* gene from *Stenotrophomonas maltophilia*, which encodes a dicamba monooxygenase (DMO) protein and provides tolerance to dicamba herbicide;
- *ft_t* gene that is a modified version of the *Rdpa* gene from *Sphingobium herbicidovorans* which encodes a 2,4-D and FOPs dioxygenase protein (FT_T). This protein provides tolerance to 2,4-D and FOPs herbicides; and a
- *cp4 epsps* gene from *Agrobacterium* sp. strain CP4, which encodes a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein and provides tolerance to glyphosate herbicide.

The applicant has indicated that food derived from MON87429 may enter the Australian and New Zealand food supply as imported food products. These may include starch, grits, meal, flour, oil and sweetener products.

1.3 The current standard

Pre-market approval is necessary before a food produced using gene technology can enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment. Standard 1.5.2 of the Code sets out the permission and conditions for the sale of food that consists of, or has as an ingredient, a food produced using gene technology (a GM food). Foods that have been assessed and approved are listed in Schedule 26 of the Code.

Section 1.5.2—4 of the Code requires food to be labelled as ‘genetically modified’ where novel DNA and/or novel protein remains present in the final food. The requirement applies to foods for sale that consist of, or have as an ingredient (including food additives and processing aids from GM sources), food that is a GM food. Standard 1.2.1 provides that the requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer - see subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

Foods listed in subsections S26—3(2), (2A) and (3) of Schedule 26 are considered to have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not produced using gene technology. Foods listed in these subsections must also be labelled with the words ‘genetically modified’, as well as any other additional labelling required by the Schedule, regardless of the presence of

novel DNA or novel protein in the foods.

The requirement to label food as 'genetically modified' does not apply to food that:

- has been highly refined (other than food that has been altered), where the effect of the refining process is to remove novel DNA or novel protein
- is a substance used as a processing aid or a food additive, where novel DNA or novel protein from the substance does not remain present in the final food
- is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%)
- is intended for immediate consumption and which is prepared and sold from food premises and vending machines, including restaurants, take away outlets, caterers, or self-catering institutions
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient.

If the GM food for sale is not required to bear a label, the labelling information in section 1.5.2—4 must accompany the food or be displayed in connection with the display of the food (in accordance with subsections 1.2.1—9(2) and (3) of Standard 1.2.1).

Subsection 1.1.1—10(8) of Standard 1.1.1 states that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

1.4 Reasons for accepting Application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

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

2 Summary of the assessment

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 26 March 2020.

A total of 33 submissions were received, of which 31 were opposed to the proposed draft variation to Schedule 26. Of these submissions, 21 were related to a campaign targeting Application A1192 by GE Free NZ and GE Free Northland. This includes a joint submission by GE Free NZ, GE Free Northland, Auckland GE Free Coalition, Gene Ethics, Physicians

and Scientists for Global Responsibility (PSGR), Safe Food Campaign, South Australian Genetic Food Information Network (SAGFIN), Pure Harvest Organic Foods, Manna Hill Estate Olive Oil, Tuckers Natural and Jonny's Popcorn. Some individuals/organisations who participated in the joint submission also provided a second submission. Four submissions were directly related to each other but do not appear to be part of a campaign.

The submitters that supported the proposed draft variation include the Victorian Department of Health and Human Services (DHHS) and the Victorian Department of Jobs, Precincts and Regions (DJPR) and New Zealand Food Safety (NZFS)

Of the submissions received, many submitters raised issues that were outside the scope of FSANZ's regulatory framework. This includes issues related to social impact, the environment, farming practices, trade, and general GM issues not directly related to FSANZ's food safety assessment.

Several submitters were concerned that seeds from MON87429 would be coated with neonicotinoid insecticides. This was associated with a [press release from GE Free NZ](#)² initiating a campaign against Application A1192, where it was claimed that the MON87429 seed is coated with "the systemic bee killing neonicotinoid insecticide". The insecticide was not specified. Neonicotinoid insecticides are prohibited in food unless they comply with specific limits referred to as Maximum Residue Limits (MRLs). These limits are applicable to foods derived from GM and non-GM foods alike and several neonicotinoid insecticides already have MRLs in the Code.

Responses to safety issues raised or implied in submissions are provided in Table 1.

² <https://press.gefree.org.nz/press/20200414.htm>

Table 1: Summary of issues raised by submissions

Issue	Raised by	FSANZ response
<p>The corn is sprayed with multiple pesticides. Cumulative and synergistic impacts are likely to increase consumer exposure to harmful pesticides.</p>	<p>Joint submission; GE Free Northland; PSGR; Grey Power Otamatea Inc; Body & Mind For Life; Tucker's natural; Private submitters (BF, CD, DF, RF, BJ, BS, DM, DR, EH & ME, FI, JC, JK, LG, MK, MM, MS, MW, RB, SL, VA)</p>	<p>The use of agricultural and veterinary (agvet) chemicals (including the excipients associated with the active constituent) is regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the New Zealand Ministry for Primary Industries (MPI). In Australia and New Zealand, residues of these chemicals are prohibited in both GM and non-GM food unless they comply with specific MRLs.</p> <p>FSANZ and the APVMA have shared responsibilities in relation to MRLs for food in Australia. Australia uses internationally agreed methodologies for establishing MRLs, including the consumer dietary exposure estimates to pesticides. This may include considering cumulative or synergistic impacts if there are known interactions or common toxicology, regardless of whether a product or commodity is GM or conventionally grown.</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, i.e., below the level that could pose health and safety risks to consumers. For further details see the FSANZ website³.</p> <p>In New Zealand, agvet chemicals must comply with New Zealand's MRLs Standards which are established by MPI. For further details see the MPI's website⁴.</p>
<p>The APVMA sets MRLs based on agronomic rather than health and safety grounds.</p>	<p>Joint submission</p>	<p>The APVMA undertakes a dietary exposure evaluation to ensure that the levels of agvet chemicals below the MRL do not pose an undue hazard to human health. The process and data requirements required by the APVMA in setting MRLs are provided on their website⁵.</p>
<p>Many FOPS herbicides are not registered with NZ MPI.</p>	<p>Joint submission; Private submitter (LG)</p>	<p>Residues of agvet chemicals are prohibited in food derived from both GM and non-GM crops unless they comply with specific MRLs. The NZ MPI website⁶ contains further information regarding MRL requirements from imported food.</p>
<p>Concern about the effects of Fluazifop-p-butyl (FPB) herbicide residues on lung health given COVID-19.</p>	<p>Private submitters (EH & ME)</p>	<p>The safety assessment applied to foods from herbicide-tolerant GM crops is the same as for other GM foods but also includes consideration of the safety of any novel metabolites that may be produced in the GM plant after a herbicide has been sprayed. The GM food safety assessment does not determine the amount of herbicide residue that is allowed to be present on a GM food or the safety of the herbicide per se. This is done separately as part of the MRL setting process and applies to both conventionally bred (non-GM) and GM crops. Residues</p>

³ <https://www.foodstandards.gov.au/consumer/chemicals/maxresidue/pages/default.aspx>

⁴ <https://www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/maximum-residue-levels-for-agricultural-compounds/>

⁵ www.apvma.gov.au

⁶ <https://www.mpi.govt.nz/growing-and-harvesting/plant-products/pesticide-maximum-residue-levels-mrls-for-plant-based-foods/>

Issue	Raised by	FSANZ response
		of agricultural and veterinary chemicals can only legally be present on food if they comply with MRLs.
Changes in plant composition following herbicide spray.	Private submitters (BF, CD, DF, RF)	The compositional analysis of MON87429 was undertaken under conditions of the intended use of the product i.e. sprayed with herbicides. Grain from MON87429, sprayed with herbicides, was analytically determined to be equivalent in composition to grain from non-GM corn.
The data FSANZ relied on in its assessment was not independent or sufficient; FSANZ did not examine safety data on potential impacts of the GM corn absorbing multiple chemicals or data on unintended mutations/effects from gene editing and transgenic engineering.	Joint submission; GE Free Northland; PSGR; Grey Power Otamatea Inc; Private submitters (BF, CD, DF, RF, BJ, BS, CM, DM, GB, FI, JC, LG, MS, SL, VA)	<p>The applicant must and did provide FSANZ with evidence of the safety of the new GM food that is the subject of the application in accordance with FSANZ data requirements. Such data must be generated according to quality assurance guidelines that are based on internationally accepted protocols (i.e. validated methodology and procedures that are consistent with Good Laboratory Practice (GLP)) and be able to stand up to external scrutiny (i.e. independent audits and documentation trails). To achieve this, the applicant submitted to FSANZ a comprehensive dossier of quality-assured raw experimental data for each GM food. This enabled FSANZ to independently assess the data and reach an independent conclusion about the safety of the food in question. In addition to the data package provided by the applicant, FSANZ had regard to information from a variety of other sources: the scientific literature, other applications, other government agencies and the public.</p> <p>The approach used by FSANZ to assess the safety of GM food, both generally and for the purposes of this application, is based on core concepts and principles developed by the Codex Alimentarius Commission (Codex 2009a, 2009b). This approach has been widely adopted and implemented around the world and ensures that approved GM foods are as safe as their non-GM counterparts.</p> <p>Regarding any potential impacts of GM corn absorbing multiple chemicals, data was provided that demonstrated that grain from MON87429, sprayed with herbicides, is equivalent in composition to grain from non-GM corn.</p> <p>The genetic modification of MON87429 is by the transgenesis method, not gene editing (Section 3.1 of the SD1).</p> <p>The occurrence of unintended changes is not a phenomenon that is specific to transgenesis, but also occurs in conventional breeding. The accumulated evidence and regulatory experience over the last 25 years does not support the hypothesis that GM foods have a greater propensity for unintended effects or that the technology is itself inherently harmful or a major source of risk to the consumer, compared to conventional forms of breeding (Herman & Price 2013, Ricroch 2013, Ladics et al 2015, FSANZ 2019).</p>
Absence of long-term animal and human feeding studies using whole corn.	Joint submission; PSGR; Private submitters (EH & ME)	FSANZ has concluded that food derived from MON87429 is equivalent to food from non-GM corn in terms of its safety. As part of the safety assessment, FSANZ did not identify any new or altered hazards as a result of the genetic modification to the corn. In the absence of any new or altered hazards, additional studies such as animal or human studies are not warranted.

Issue	Raised by	FSANZ response
		<p>FSANZ convened a workshop in 2007⁷ to examine the usefulness of animal feeding studies using whole foods to support the safety assessment of GM foods. In terms of long-term safety of a GM food, it was concluded that such studies generally do not contribute meaningful information. There were only limited circumstances where such studies may be informative, for example in the case of nutritional modification. Therefore, for most GM foods, including those derived from MON87429, feeding trials of any length are unlikely to contribute any further useful information to the safety assessment and are not warranted (Sánchez & Parrott, 2017). There are also ethical concerns regarding the use of animals for feeding studies when clearly identified compositional differences are absent (Bartholomaeus et al., 2013).</p>
<p>Insufficient evidence to demonstrate lack of allergenicity.</p>	<p>Joint submission; Private submitter (SB)</p>	<p>Only a small number of dietary proteins have the potential to impair health, because they have anti-nutrient properties or they can cause allergies in some consumers (Delaney et al., 2008). There is no credible scientific basis to support the notion that food allergies are linked to the introduction of any GM crops or that allergens can arise spontaneously as a result of the genetic modification process (Goodman and Tetteh, 2011).</p> <p>The assessment approach used by FSANZ for GM foods, including MON87429, includes procedures for the assessment of potential allergenicity of any new proteins that are expressed as a result of the genetic modification. The approach relies on various criteria which together provide a weight of evidence regarding the potential allergenicity of a new protein. These criteria include the source of the protein, amino acid sequence similarity to known allergens, stability to heat and resistance to digestion.</p> <p>For the purposes of this application, data that matches these criteria was examined in Section 4 of the SD1 and contributes to the weight of evidence which indicates the introduced proteins in MON87429 are unlikely to be allergenic to humans and raise no food safety concerns.</p>
<p>The evidence and impact of the susceptibility of the introduced proteins to heat and digestive enzymes; Absorption of bacterial enzymes into human organs and tissues.</p>	<p>Joint submission; Private submitter (FI)</p>	<p>All proteins that are consumed are subject to the same digestive processes. This is irrespective of their source or function, including novel proteins expressed in GM foods. Susceptibility to digestion is one of a number of parameters that are used in a weight of evidence approach to assess the potential allergenicity risk of a new protein in the food. Stability to heat is another parameter that is also used.</p> <p>Section 4 of the SD1 reviews evidence from a number of studies related to the susceptibility of the introduced DMO, PAT, FT_T and CP4 EPSPS proteins to heat and digestive enzymes, as well as other information relevant to an assessment of potential allergenicity. These studies indicate the introduced proteins are unlikely to be allergenic and do not raise any food safety concerns.</p>
<p>Survival of foreign DNA following digestion</p>	<p>Joint submission; Private</p>	<p>There is no difference in terms of risk between foreign DNA and the DNA already present in our diet. This issue</p>

⁷ <http://www.foodstandards.gov.au/consumer/gmfood/pages/roleofanimalfeedings3717.aspx>

Issue	Raised by	FSANZ response
(Netherwood et al., 2004) and its safety; transfer of foreign DNA among gut bacteria.	submitter (CM)	has been considered in detail by FSANZ and a summary is available on the FSANZ website ⁸ . The Netherwood et al 2004 study has been previously considered by FSANZ ⁹ .
MON87429 corn contains a dsRNA gene edit that has not been evaluated.	Joint submission	MON87429 does not contain novel dsRNA. As described in Section 3.2.4 of the SD1, the cp4 epsps expression cassette contains a partially modified non-coding sequence from corn. This sequence is recognised and targeted by an endogenous male tissue-specific small interfering RNA (siRNA) to degrade cp4 epsps mRNA in corn male tissue (Yang et al., 2018). This results in a MON87429 plant that is tolerant to glyphosate but produces a non-viable pollen phenotype. Like all sequences transformed into MON87429, the siRNA target sequence is included in FSANZ's evaluation.
Oppose the propagation of the GM corn in Australia and New Zealand.	Private submitter (FI)	The approval of MON87429 corn for the purposes of this application would not allow GM corn to be cultivated in Australia and New Zealand. This would require separate regulatory assessment and approval, by the Office of the Gene Technology Regulator (OGTR) in Australia and by the Environmental Protection Authority (EPA) in New Zealand.
The 14 day acute toxicity study showed a significant effect of CP4 EPSPS digestion on female reproductive systems (hydrometra) but the results were dismissed as biologically unimportant.	Joint submission	The safety of the CP4 EPSPS protein is well established. There is no evidence of acute toxicity in mice following a single oral dose of up to 400 mg/kg of CP4 EPSPS protein. The maximum dose level is far in excess of the level of exposure expected from the consumption of GM corn. The effects on the hydrometra referred to in the Joint Submission were observed in female mice from both treated and control groups, and therefore, those effects are not related to the CP4 EPSPS protein.
FSANZ ignores the 5 different transgenes and their effect on the corn's phenotype that may have health impacts; combined effects of recombinant proteins.	Joint submission; Private submitter (LG)	MON87429 contains 4 transgenes. The compositional analysis (Section 5 of the SD1) determines if, as a result of the genetic modification, any unexpected changes to composition of the food has occurred. Constituents most relevant to the safety of the food or that may have an impact on the whole diet are examined. FSANZ concluded MON87429 corn is compositionally equivalent to food derived from non-GM corn.

⁸ <http://www.foodstandards.gov.au/consumer/gmfood/recombinantdna/Pages/default.aspx>

⁹ <https://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx>

Issue	Raised by	FSANZ response
<p>FSANZ's assessment disregards significant changes to key components of the corn (e.g. total fatty acids and minerals) and fails to meet its own requirement for additional nutritional studies.</p>	<p>Joint submission</p>	<p>FSANZ considered a number of constituents in corn that are important for a compositional analysis (OECD 2002). While statistically significant changes were observed in a few constituents (e.g. total fatty acids and minerals), mean values were well within the range of natural variation typical for non-GM corn and were not considered to be biologically significant.</p> <p>Additional nutritional studies to assess the potential impact of compositional changes on the whole diet would only be considered if biologically significant changes to the levels of certain nutrients had occurred. Such changes were not observed in this case, therefore additional studies are unnecessary.</p>
<p>MON87429 was not evaluated for the production of the metabolites tetrahydrofuran diols (THF-diols) that may have serious health implications.</p>	<p>Joint submission</p>	<p>The approach to the compositional analyses of GM food is a targeted one. Rather than analysing every possible constituent, which would be impractical, the aim is to analyse only those constituents most relevant to the safety of the food or that may have an impact on the whole diet.</p> <p>The Organisation for Economic Co-operation and development (OECD) publishes internationally recognised consensus documents on compositional considerations for various crops. These documents specify which constituents (nutrients, anti-nutrients, toxicants and secondary metabolites) are most relevant for human health. THF-diols or their metabolites are not considered to be key constituents for the compositional analysis of corn.</p> <p>In relation to specific concerns about THF-diols in corn, FSANZ's investigation indicates there is only limited evidence of toxicity <i>in vitro</i> or in animal studies using the oral route of exposure.</p> <p>FSANZ notes that THF-diols would be present in both non-GM and GM corn. Furthermore, unless a deliberate change to crop composition has been made, significant compositional differences between GM and non-GM comparators tend to be small and usually within the range that would be expected for other non-GM varieties. There is no plausible basis to investigate the levels of THF-diols or their metabolites MON87429 corn.</p> <p>FSANZ also notes that THF-diols are derivatives of linoleic acid, the most highly consumed polyunsaturated fatty acid in the human diet which can be found in vegetable oil, nuts, seeds, meats and eggs (Whelan & Fritsche, 2013; Moghaddam et al., 1996). The level of linoleic acid in MON87429 was within the range of other non-GM varieties.</p>
<p>Targeted serum screen tests were not completed.</p>	<p>Joint submission</p>	<p>Specific serum screening would only be considered if a newly expressed protein is derived from a source known to be allergenic or if it has amino acid sequence similarity with a known allergen. Neither of these criteria applied in this case. For more information please see the FSANZ application handbook¹⁰.</p>

¹⁰ <https://www.foodstandards.gov.au/code/changes/Pages/applicationshandbook.aspx>

Issue	Raised by	FSANZ response
Products from the GM corn will not be labelled.	Joint submission; GE Free Northland; Grey Power Otamatea Inc; Private submitters (DM, LG, MK, MW, SB, TU)	Labelling requirements in the Code for approved GM foods will apply so food for sale that consists of, or has as an ingredient, MON87429 corn, will be required to be labelled as 'genetically modified' if the food contains novel DNA or novel protein, as outlined and discussed in Section 2.3.1 of this Report.
General safety concern of GM foods e.g. on the human immune system.	GE Free Northland; Grey Power Otamatea Inc; Tucker's natural; Private submitters (BS, CM, FI, GB, JC, JK, LG, MK, MM, MS, MW, PF, RB, SB, SL)	<p>Many concerns regarding the safety of GM foods can be traced back to a handful of studies reporting adverse effects in animals. A response by FSANZ¹¹ to some of these studies is already available on our website. Further analyses of some of the other studies can be found in Snell et al (2012), Ricroch (2013) and Ricroch <i>et al</i> (2014).</p> <p>FSANZ conducts a thorough safety assessment of all GM foods before they are allowed in the food supply. This assessment ensures that any approved GM foods are as safe and nutritious as comparable non-GM foods already in the Australian and New Zealand food supply. Further information can be found on the FSANZ webpage¹².</p>
The decision to allow MON87429 is undemocratic whilst New Zealanders are pre-occupied with dealing with the Covid-19 crisis and would breach Treaty of Waitangi obligations by failing to consult with Tangata Whenua as well as the wider population.	Private submitter (DR)	FSANZ followed the standard public consultation process for this application that is used for all other applications. The public comment period is generally 6 weeks, however because of the current COVID-19 situation, this was extended to 8 weeks. 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. Approximately 7,000 subscribers and interested parties were notified.

¹¹ <http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx>

¹² <https://www.foodstandards.gov.au/consumer/gmfood/gmoverview/Pages/default.aspx>

2.2 Safety assessment

The safety assessment of MON87429 is provided in 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 corn line MON87429 was restricted to human food safety and nutritional issues. This assessment therefore does not address any risks to the environment that may occur as the result of growing GM plants used in food production, or any risks to animals that may consume feed derived from GM plants. Cultivation in Australia or New Zealand would require separate regulatory assessment and approval, by the Office of the Gene Technology Regulator (OGTR) in Australia and by the Environmental Protection Authority (EPA) in New Zealand.

Some minor changes to the SD1 were made to correct small typographical and table errors.

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 corn line MON87429 is considered to be as safe for human consumption as food derived from non-GM corn cultivars.

2.3 Risk management

2.3.1 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see Section 1.3 of this Report), food derived from MON87429 will be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein or is listed in subsections S26—3(2), (2A) and (3) of Schedule 26 as being subject to the condition that the labelling must comply with section 1.5.2—4 of Standard 1.5.2 (such food has altered characteristics). FSANZ has determined that food derived from MON87429 does not have altered characteristics.

MON87429 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 line MON87429 will be unlikely to require labelling as 'genetically modified'.

MON87429 products such as flour and meal (used in bread and polenta) and grits (used in cereals) would be likely to contain novel protein or novel DNA, and if so, would require labelling as 'genetically modified'. Sweet corn kernels consisting of MON87429 corn are also likely to require labelling.

The requirements for labelling as 'genetically modified' differ depending on whether the GM food is an ingredient of the food for sale or not. For example, corn flour derived from

MON87429 that is for retail sale will require the labelling statement.

However, FSANZ notes that MON87429 products may be used to manufacture a food that is not itself a food for sale, but is used as an ingredient in foods for retail sale or in food sold to a caterer (for example, corn flour derived from MON87429 is used to make a corn pasta and the pasta is then used as an ingredient in a ready meal). As such, these ingredients are not GM foods and are not subject to labelling requirements set out in subsection 1.5.2—4(1).

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-Committee¹³ to identify and evaluate appropriate methods of analysis associated with all Applications to FSANZ, including those Applications for food produced using gene technology (GM Applications).

The EAG indicated that for GM Applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the Applicant for A1192.

2.4 Risk communication

2.4.1 Consultation

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 requested 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 26 March 2020 and 21 May 2020. 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.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on this Application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of the safety assessment.

Documents relating to Application A1192, including submissions received, are available on the FSANZ website.

2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act.

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new GM foods

¹³ Now known as the Implementation Subcommittee for Food Regulation

(OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as varying Schedule 26 is a consequential change of maintaining a permitted schedule of GM foods. Additionally, permitting new GM foods is deregulatory as using the GM technology will be voluntary if the application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the Application). This analysis considers permitting food from herbicide-tolerant corn line MON87429. A consideration of costs and benefits was included in the call for submissions (CFS) report based on the information and data held at that time. No further information has been received in the consultation process to date that influenced the findings from the analysis of costs and benefits in the CFS.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting food derived from MON87429.

Costs and benefits of permitting food derived from MON87429

Foods derived from MON87429 would be permitted under the Code, allowing broader market access and increased choice in raw materials. For those MON87429 food products containing novel DNA or novel protein, required labelling would allow consumers wishing to avoid these products to do so.

Due to the voluntary nature of the permission, manufacturers and retailers will only engage with corn line MON87429 where they believe a net benefit exists.

Cost savings to industry may put downward pressure on prices.

Permitting food derived from MON87429 may result in a small cost to government in terms of adding it to the current range of GM foods that are monitored for labelling compliance.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting food derived from herbicide-tolerant corn line MON87429 most likely outweigh the associated 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 varying Schedule 26 as a result of Application A1192.

2.5.1.3 Any relevant New Zealand standards

Standard 1.5.2 and Schedule 26 apply in both Australia and New Zealand. There are no

relevant New Zealand Standards.

2.5.1.4 Any other relevant matters

The applicant has submitted applications for regulatory approval of MON87429 to a number of other countries, as listed in Table 2.

The applicant has stated they currently have no intention to apply for approval to cultivate MON87429 in Australia and New Zealand. Cultivation in Australia or New Zealand would require independent assessment and approval by the OGTR and NZ EPA, respectively.

Table 2: List of countries to whom applications for regulatory approval of MON87429 have been submitted

Country	Agency	Type of approval sought	Status
Argentina	National Food Safety and Quality Service	Food and Feed	Under review
Canada	Canadian Food Inspection Agency	Environmental release and cultivation	Approved
	Canadian Food Inspection Agency	Feed	Approved
	Health Canada	Food	Approved
European Union	European Food Safety Authority	Food and Feed	Under review
Japan	Ministry of Health, Labor and Welfare	Food	Under review
	Ministry of Agriculture, Forestry and Fisheries	Feed	Under review
	Ministry of Agriculture, Forestry and Fisheries / Ministry of the Environment	Environment	Under review
Korea	Ministry of Food and Drug Safety	Food	Under review
	Rural Development Administration	Feed	Under review
Taiwan	Food and Drug Administration, Ministry of Health and Welfare	Food	Under review
	Council of Agriculture	Feed	Under review
United States	United States Department of Agriculture	Environmental release and cultivation	Under Review
	Food and Drug Administration	Food and feed	Under Review

Further other relevant matters are considered below.

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 MON87429 has been assessed based on the data requirements provided

in the FSANZ [Application Handbook](#)¹⁴ which, in turn reflect internationally-accepted GM food safety assessment guidelines. 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 MON87429 is considered as safe as food derived from other non-GM corn lines.

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 in the Code, food derived from MON87429 would be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein (see Section 2.3.1 of this Report).

2.5.2.3 The prevention of misleading or deceptive conduct

The provision of detection methodology by the applicant (as described in Section 2.3.2 of this Report) addresses this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex, 2009a). Based on these principles, the risk analysis undertaken for MON87429 used the best scientific evidence available. The applicant submitted a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the applicant, other available resource material including published scientific literature and general technical information was used in the safety assessment.

- **the promotion of consistency between domestic and international food standards**

This is not a consideration as there are no relevant international standards.

- **the desirability of an efficient and internationally competitive food industry**

The inclusion of GM foods in the food supply, providing there are no safety concerns, allows for innovation by developers and a widening of the technological base for producing foods. Corn line MON87429 is a new food crop designed to expedite future breeding efforts as well as providing growers with alternative weed management strategies.

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

Issues related to consumer information and safety are considered in Sections 2.2 and 2.3 of this Report.

- **any written policy guidelines formulated by the Forum on Food Regulation**

No specific policy guidelines have been developed.

¹⁴ <http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

3 References

- Bartholomaeus A, Parrott W, Bondy G, Walker K (2013) The use of whole food animal studies in the safety assessment of genetically modified crops: Limitations and recommendations. *Crit Rev Toxicol* 43(S2):1–24
- Codex (2009a) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome. <http://www.fao.org/3/a1554e/a1554e00.htm>
- Codex (2009b) Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants. CAC/GL 45-2003. Codex Alimentarius Commission, Rome. <http://www.fao.org/3/a1554e/a1554e00.htm>
- Delaney B, Astwood JD, Cunny H, Eichen Conn R, Herouet-Guicheney C, MacIntosh S, Meyer LS, Privalle LS, Gao Y, Mattsson J, Levine M, ILSI (2008) Evaluation of protein safety in the context of agricultural biotechnology. *Food Chem Toxicol* 46:S71-S97
- FSANZ (2019) Final report – Review of food derived using new breeding techniques. <https://www.foodstandards.gov.au/consumer/gmfood/Documents/NBT%20Final%20report.pdf>
- Goodman RE, Tetteh AO (2011) Suggested Improvements for the Allergenicity Assessment of Genetically Modified Plants Used in Foods. *Curr Allergy Asthma Rep* 11:317-324
- Herman RA, Price WD (2013) Unintended Compositional Changes in Genetically Modified (GM) Crops: 20 Years of Research. *J. Agric. Food Chem* 61(48):11695–11701
- Ladics GS, Bartholomaeus A (2015) Genetic basis and detection of unintended effects in genetically modified crop plants. *Transgenic Res* 24:587–603
- Moghaddam M, Motoba K, Borhan B, Pinot F, Hammock BD (1996) Novel Metabolic Pathways for Linoleic and Arachidonic Acid Metabolism. *Biochim Biophys Acta* 13;1290(3):327-39
- OECD (2002) Consensus document on compositional considerations for new varieties of maize (*Zea mays*): Key food and feed nutrients, anti-nutrients and secondary plant metabolites. Organisation for Economic Co-operation and Development, Paris. [http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono\(2002\)25&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono(2002)25&doclanguage=en)
- Ricroch AE (2013) Assessment of GE food safety using '-omics' techniques and long-term animal feeding studies. *N Biotechnol* 30(4):349–354
- Ricroch AE, Boisron A, Kuntz M (2014) Looking back at safety assessment of GM food/feed: an exhaustive review of 90-day animal feeding studies. *Int J Biotechnol* 13(4):230–256
- Sánchez MA, Parrott W (2017) Characterization of scientific studies usually cited as evidence of adverse effects of GM food/feed. *Plant Biotechnol J* 15(10):1227-1234
- Snell C, Bernheim A, Bergé J, et al (2012) Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: A literature review. *Food Chem Toxicol* 50(34):1134–1148
- Whelan J, Fritsche K (2013) Linoleic Acid. *Adv Nutr* 1;4(3):311-2
- Yang H, Qi Y, Goley ME, Huang J, Ivashuta S, Zhang Y, Sparks OC, Ma J, van Scoyoc BM, Caruano-Yzermans AL, King-Sitzes J, Li X, Pan A, Stoecker MA, Wiggins BE, Varagona MJ (2018) Endogenous tassel-specific small RNAs-mediated RNA interference enables a novel glyphosate-inducible male sterility system for commercial production of hybrid seed in *Zea mays* L. *PLoS ONE* 13:e0202921

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

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



Food Standards (Application A1192 – Food derived from herbicide-tolerant corn line MON87429) 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 variation commences on the date specified in clause 3 of the variation.

Dated [To be completed by the delegate]

Scott Crerar
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 A1192 – Food derived from herbicide-tolerant corn line MON87429) 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] Schedule 26 is varied by inserting in the table to subsection S26—3(4) in alphabetical order under item 2

(zb) herbicide-tolerant corn line MON87429

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.

The Authority accepted Application A1192 which seeks approval for food derived from herbicide-tolerant corn line MON87429. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, 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 *Legislation Act 2003*.

2. Purpose

The Authority has approved the draft variation amending Schedule 26 of the Code to permit the use or sale of food derived from herbicide-tolerant corn line MON87429.

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 A1192 will include one round of public consultation following an assessment and the preparation of a draft variation.

A Regulation Impact Statement was not required because the sale of food derived from corn line MON87429, if approved, would be voluntary and would be likely to have a minor impact on business and individuals (see OBPR ref 12065).

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

Item [1] inserts new paragraph (zb) into item 2 in the table to subsection S26—3(4) in Schedule 26. The new paragraph refers to herbicide-tolerant corn line MON87429. The effect of the variation is to permit the sale of food derived from that corn line in accordance with Standard 1.5.2.