26 March 2024
286-24

Approval report – Application A1276

Food derived from herbicide-tolerant soybean line MON94313

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Bayer CropScience Proprietary Limited seeking to amend the Australia New Zealand Food Standards Code to permit the sale and use of food derived from a new food produced using gene technology: soybean line MON94313. This soybean line has been genetically modified for tolerance to the herbicides dicamba, glufosinate, 2,4-D and mesotrione.

On 30 October 2023, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 13 March 2024. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 26 March 2024.

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

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website[2]:

SD1 Supporting Document 1 – Safety assessment report

[2] https://www.foodstandards.gov.au/food-standards-code/applications/A1276-Food-derived-from-herbicide-tolerant-soybean-line-MON94313

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from Bayer CropScience Proprietary Limited to request a variation to Schedule 26 in the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): soybean line MON94313. Soybean line MON94313 has been genetically modified for tolerance to the herbicides dicamba, glufosinate, 2,4-D and mesotrione.

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*, is the protection of public health and safety. Accordingly, the safety assessment is a critical part of the assessment approval process for all GM food applications.

The safety assessment of soybean line MON94313 is in Supporting Document 1 (SD1). The assessment found no potential public health or safety concerns. Based on the data provided by the applicant and other information, food derived from soybean line MON94313 is considered to be as safe for human consumption as food derived from conventional non-GM soybean varieties.

Existing labelling requirements for GM food will apply to food derived from soybean line MON94313 in accordance with the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 30 October 2023. Three submissions were received in the six-week consultation period. FSANZ has had regard to these submissions.

For reasons set out in this report, FSANZ has decided to approve the draft variation proposed at the call for submissions without change. The approved draft variation will amend Schedule 26 of the Code to include a new item 7(s) in the table to subsection S26—3(4) containing a reference to ‘herbicide-tolerant soybean line MON94313’. The effect of the approved draft variation will be to permit the sale and use of food derived from this soybean line in accordance with the Code.

1 Introduction

1.1 The applicant

Bayer CropScience Proprietary Limited is a technology provider to a number of sectors including the agriculture sector.

1.2 The application

Application A1276 was submitted on 16 May 2023. It seeks an amendment to the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): soybean line MON94313. This soybean line has been genetically modified (GM) for tolerance to the herbicides dicamba, glufosinate, 2,4-D and mesotrione. MON94313 expresses 4 novel substances, summarised in Table 1.

Table 1: Novel substances expressed in MON94313

Protein	Gene	Donor organism	Function	Previously assessed by FSANZ?
Dicamba mono-oxygenase (DMO)	*dmo*	*Stenotrophomonas maltophilia*	Dicamba tolerance	Yes (5 previous applications)
Phosphinothricin acetyltransferase (PAT)	*pat*	*Streptomyces viridochromogenes*	Glufosinate tolerance	Yes (30 previous applications)
FT_T.1	*ft_t.1*	*Sphingobium herbicidovorans*	2,4-D tolerance	Yes (similar protein; A1192)
Triketone dioxygenase (TDO)	*TDO*	*Oryza sativa*	Mesotrione tolerance	No

1.3 The current standard

Pre-market approval is necessary before GM foods 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 sale of food that consists of, or has as an ingredient, a GM food. Foods that have been assessed and approved are listed in Schedule 26 of the Code.

Subject to the exceptions listed below, section 1.5.2—4 requires food to be labelled as 'genetically modified' where novel DNA or novel protein is present in the food for sale.

Additionally, foods listed in subsections S26—3(2), (2A) and (3) of Schedule 26 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. These foods 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.

The requirement to label as 'genetically modified' applies to a food for sale that consists of, or has as an ingredient (including food additives and processing aids), food that is a *genetically modified food*[3]. The requirements imposed by section 1.5.2—4 apply to foods for retail sale and to foods sold to a caterer in accordance with Standard 1.2.1.

The labelling requirement in section 1.5.2—4 does not apply if the GM food:

- has been highly refined (other than food that has an altered characteristic), 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 food for sale;
- is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%); or
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient.

The above labelling requirement also does not apply if the food for sale is intended for immediate consumption and is prepared and sold from food premises and vending vehicles, including restaurants, take away outlets, caterers or self-catering institutions.

If the food for sale is a food not required to bear a label and is not in a package, 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 *Food Standards Australia New Zealand Act 1991* (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

For reasons set out in this report, the draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved

[3] Subsection 1.5.2—4(5) defines ***genetically modified food*** to mean 'a *food produced using gene technology that

a) contains novel DNA or novel protein; or
b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section' (*that being section 1.5.2—4*).

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 findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 30 October 2023. The consultation period was six weeks.

Three submissions were received. Two of these – from New Zealand Food Safety (NZFS) and New Zealand Food and Grocery Council (NZFGC) – supported the proposed draft variation to Schedule 26, and did not raise any issues. The third, from a private individual, opposed the proposed draft variation and raised a number of issues which are summarised in Table 2. Some of the issues raised were outside the scope of FSANZ's regulatory remit, such as issues relating to the environmental risks of GM crops, and general GM issues not directly related to FSANZ's food safety assessment.

Responses to issues raised in submissions are provided in Table 2.

Table 2: Summary of issues

Issue	Raised by	FSANZ response
The submitter stated that "no major DNA rearrangement" was observed but that minor DNA rearrangements may have impacts on humans or animals.	Private submitter (S.R.)	The statement quoted by the submitter, that "no major DNA rearrangement" was observed in this soybean line, is not found in the application or in FSANZ's safety assessment. Section 3.4.3 of the safety assessment report (SD1) states that the DNA inserted into this soybean line is organised as expected, and that no deletions, insertions, mutations or rearrangements of the expression cassettes were detected.
This soybean line is intended to be bred with other GM soybean varieties to create new combinations of traits – no testing has been carried out on the resultant varieties.	Private submitter (S.R.)	Combining traits or genes of interest into a single plant line is referred to as stacking. No separate approval or safety assessment is required for foods from a stacked GM plant line if the individual GM parent lines have already undergone separate safety assessment and approval. Food from the parent lines must be listed in Schedule 26 of the Code. Crossing two or more approved GM plants, using conventional breeding, is unlikely to pose any new or additional food safety risks over and above what was previously considered in the safety assessment of each individual parental GM line. In addition, all new crop varieties undergo comprehensive testing of their phenotypic characteristics during the development process to ensure commercial suitability. This testing provides additional assurance for the absence of any significant unintended effects in stacked GM lines. For more information please refer to the following webpage[4].

[4] https://www.foodstandards.gov.au/consumer/gmfood/stackedgene

Issue	Raised by	FSANZ response
Testing of the proteins expressed in MON94313 is too limited, and the proteins are not sufficiently identical to the proteins that have undergone safety tests.	Private submitter (S.R.)	FSANZ does not agree. FSANZ remains satisfied that the safety testing undertaken was appropriate and reliable, and has assessed the data provided according to the principles and guidelines used for all GM foods. FSANZ has previously assessed proteins identical to the DMO and PAT proteins, and as such only an updated bioinformatic comparison of these proteins to known allergens or toxins was required (refer to section 3.5.1 of the *Application Handbook*). The previous assessments of the DMO and PAT proteins by FSANZ remain relevant and reliable. A full data package was provided for the FT_T.1 and TDO proteins, including a panel of analytical tests to demonstrate the equivalence of the bacterially-expressed versions of these proteins used for safety testing with those expressed in MON94313. Refer to sections 4.3 and 4.4 of the safety assessment report (SD1) for further detail.
Unintended outcomes may result from genetic modification of plants.	Private submitter (S.R.)	FSANZ notes this concern. The occurrence of unintended outcomes is not specific to genetic modification, and also occurs in conventional breeding. The accumulated evidence and regulatory experience from 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 and Price 2013; Ricroch 2013; Ladics et al. 2015; Schnell et al. 2015; FSANZ 2019; FSANZ 2021).
A concern that fragments of DNA from food enter the bloodstream and organs.	Private submitter (S.R.)	FSANZ notes this concern. DNA is a natural component of the human diet, being present to varying degrees in foods derived from plants and animals. The human body does not distinguish between DNA from GM foods (i.e. recombinant DNA) and other DNA that is naturally present in a wide variety of foods. Both types of DNA are chemically indistinguishable and are extensively broken down during digestion. Some DNA fragments may remain which can be detected in the digestive tract, and which have also been shown to pass into the bloodstream and other body tissues. There is no scientifically plausible basis to expect that recombinant DNA would have different impacts on the human body compared to other DNA in the diet. This issue has been considered in detail by FSANZ and a summary is available on the FSANZ website[5].

[5] https://www.foodstandards.gov.au/consumer/gmfood/safety-of-ingested-recombinant-DNA

Issue	Raised by	FSANZ response
Long-term and intergenerational studies on the safety of GM crops and food have not been carried out.	Private submitter (S.R.)	FSANZ notes this concern. GM food has been in our food supply for over 25 years. During this time, safety assessments by FSANZ and other agencies, as well as a large body of peer-reviewed research, has shown that approved GM foods are as safe to eat as non-GM foods. FSANZ's assessment has concluded that food derived from soybean line MON94313 is equivalent to food from conventional non-GM soybean in terms of its safety, including in the long-term. Additional studies would not add any useful information.

2.2 Safety assessment

The safety assessment of soybean line MON94313 is provided in Supporting Document 1 (SD1) and included the following key elements:

- a characterisation of the transferred genetic material, its origin, function and stability in the soybean genome
- characterisation of novel nucleic acids and protein in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes
- assessment of the potential for any newly expressed protein to be either allergenic or toxic in humans.

In conducting the safety assessment, FSANZ had regard to information from a variety of sources including, but not limited to, a data package provided by the applicant (application and study reports), the scientific literature and other applications.

The assessment of soybean line MON94313 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 soybean line MON94313, or any risks to animals that may consume feed derived from soybean line MON94313. Permission to cultivate soybean line MON94313 in Australia or New Zealand would require separate regulatory assessment and approval by the Gene Technology Regulator (GTR)[6] in Australia and the Environmental Protection Authority (EPA)[7] in New Zealand.

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 soybean line MON94313 is considered to be as safe for human consumption as food derived from non-GM soybean cultivars.

2.3 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation during a period of six weeks.

[6] The Office of the Gene Technology Regulator (OGTR) provides administrative support to the Gene Technology Regulator in the performance of functions under the *Gene Technology Act 2000.*
[7] The EPA implements and enforces the *Hazardous Substances and New Organisms* (HSNO) *Act 1996*.

The risk management options available to FSANZ following the call for submissions are to either:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

Having regard to all submissions received, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment without change (see Attachment A).

2.3.1 Regulatory approval

Soybean line MON94313 is a GM food for Code purposes as it is developed from 'an organism which has been modified by gene technology'[8]. The approved draft variation will list soybean line MON94313 in the table to subsection S26—3(4). This amendment will effectively provide permission for the sale and use of food derived from soybean line MON94313 as a GM food in accordance with the Code.

Subject to and in accordance with the draft variation, food derived from soybean line MON94313 may enter the Australian and New Zealand food supplies as imported food products. These may include soybean oil, milk, flour, meal, protein isolates and processed products.

Cultivation of soybean line MON94313 would require separate prior assessment and approval by the GTR in Australia and the EPA in New Zealand.

2.3.2 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see section 1.3 of this report), food for sale derived from a GM food such as soybean line MON94313 will be required to be labelled as 'genetically modified' if, among other things, the GM food:

- contains novel DNA or novel protein; or
- is listed in subsection S26—3(2), (2A) or (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 soybean line MON94313 does not have altered characteristics (see sections 5 and 6 of SD1).

Refined products from soybean line MON94313 such as soybean oil are unlikely to contain any novel DNA or novel protein and will be unlikely to require labelling as 'genetically modified'.

Products derived from soybean line MON94313 such as soy milk, flour, meal and protein isolates will likely contain novel DNA or novel protein, and if so, will require labelling as 'genetically modified'.

Section 1.5.2—4 of the Code generally requires a food for sale that consists of a GM food or has a GM food as an ingredient to be labelled as 'genetically modified', unless one of the exemptions listed in that subsection apply. Where required, the label statement 'genetically

[8] ***Food produced using gene technology*** is defined in subsection 1.1.2—2(3) of the Code as 'a food which has been derived or developed from an organism which has been modified by gene technology'.

modified' must be made in conjunction with the name of the GM food (subsection 1.5.2—4(2)). If the GM food is present in the food for sale as an ingredient, this statement may be included in the statement of ingredients (subsection 1.5.2—4(3)).

2.3.3 Detection methodology

An Expert Advisory Group (EAG) comprising laboratory personnel and representatives of Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee[9] 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[10]-based detection method. This sequence information was supplied by the applicant for A1276.

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 were invited on a draft variation which was released for public comment between 30 October 2023 and 11 December 2023. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standards News. Subscribers and interested parties were also notified.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on applications to amend the Code. All submissions are considered as part of the decision making process by FSANZ. All comments are valued and contribute to the rigour of our assessment.

Documents relating to A1276, including the received submissions, are available on the FSANZ website[11].

The draft variation was considered for approval by the FSANZ Board having regard to all the submissions made during the call for submissions period.

2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ 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

Changes have been made to the Impact Analysis requirements by the Office of Impact

[9] Now known as the Implementation Subcommittee for Food Regulation.
[10] Polymerase Chain Reaction.
[11] https://www.foodstandards.gov.au/food-standards-code/applications/A1276-Food-derived-from-herbicide-tolerant-soybean-line-MON94313

Analysis (OIA)[12]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for applications relating to GM foods, previous OIA reference number: 12065. This is because applications relating to permitting the use of GM foods that have been determined to be safe are considered to be minor and deregulatory in nature, as the use of the GM food will be voluntary if the draft variation related to the application is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

FSANZ, however, gave 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 was 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 considered permitting the sale and use of food derived from soybean line MON94313.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. The consideration of the costs and benefits in this section was 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 sought to highlight the likely positives and negatives of moving away from the status quo by permitting the sale and use of food derived from soybean line MON94313.

Costs and benefits of permitting the sale and use of food derived from soybean line MON94313

The sale and use of foods derived from soybean line MON94313 will be permitted under the Code, allowing broader market access and increased choice in raw materials. For those food products containing novel DNA or novel protein from soybean line MON94313, labelling will be required to assist consumers wishing to avoid these products to do so.

Due to the voluntary nature of the permission, manufacturers and retailers would only engage with foods derived from soybean line MON94313 where they believe a net benefit exists for them. Part of any cost savings to industry may be passed onto consumers.

There may be small and likely inconsequential costs of monitoring an extra GM food ingredient for regulators to ensure compliance with labelling requirements.

Conclusions from cost benefit considerations

FSANZ's assessment at the call for submissions stage was that the direct and indirect benefits that would arise from permitting the sale and use of food derived from soybean line MON94313 would most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

2.5.1.2 Other measures

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

[12] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

2.5.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

Cultivation in Australia or New Zealand would require independent assessment and approval by the GTR and EPA, respectively.

The applicant has submitted applications for regulatory approval of corn line DP915635 to other countries, as listed in Table 3.

Table 3: List of countries to whom applications for regulatory approval of MON94313 have been submitted

Country	Authority	Type of approval sought	Status
Brazil	National Biosafety Committee (CTNBio)	Food, Feed, Environment	Submitted
Canada	Health Canada (HC)	Food	Approved
	Canadian Food Inspection Agency (CFIA)	Feed and Environment	Approved
China	Ministry of Agriculture and Rural Affairs (MARA)	Food and Feed	Submitted
European Union	European Food Safety Authority (EFSA)	Food and Feed	Submitted
Indonesia	National Agency of Drug and Food Control (BPOM)	Food	Submitted
	Ministry of Agriculture (MOA)	Feed	Submitted
Japan	Ministry of Health, Labour and Welfare (MHLW)	Food	Submitted
	Ministry of Agriculture, Forestry and Fisheries (MAFF)	Feed	Submitted
Korea	Ministry of Food and Drug Safety (MFDS)	Food	Submitted
	Rural Development Administration (RDA)	Feed	Submitted
Malaysia	Ministry of Natural Resources, Environment (NRECC)	Food, Feed, Processing	Submitted
Paraguay	Ministry for Agriculture and Livestock (CONBIO)	Food, Feed, Environment	Submitted

Singapore	Singapore Food Agency (SFA)	Food, Feed, Processing	Submitted
Taiwan	Taiwan Food and Drug Administration (TFDA)	Food	Submitted
	Council of Agriculture (COA)	Feed	Submitted
Thailand	Thailand Food and Drug Administration (TFDA)	Food, Feed, Processing	Submitted
United States	Food and Drug Administration (FDA)	Food and feed	Submitted
	United States Department of Agriculture (USDA)	Environment	Approved

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

FSANZ's assessment did not identify any public health and safety concerns with food derived from soybean line MON94313. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from soybean line MON94313 is as safe for human consumption as food derived from conventional non-GM soybean varieties.

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

Existing labelling requirements for GM food will apply to food derived from soybean line MON94313 in accordance with the Code to enable informed consumer choice (see section 2.3.2).

2.5.2.3 The prevention of misleading or deceptive conduct

The provision of DNA sequence information by the applicant (as described in section 2.3.3) 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, 2009). Based on these principles, the risk analysis undertaken by FSANZ for soybean line MON94313 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 by FSANZ in the safety assessment.

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

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. Soybean line MON94313 is a new food crop designed for tolerance to the herbicides dicamba, glufosinate, 2,4-D and mesotrione.

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

Issues related to consumer information and safety are considered in sections 2.2 and 2.3 above.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

No specific policy guidelines have been developed.

3 Draft variation

The approved draft variation to the Code is at Attachment A and is intended to take effect on the date of gazettal.

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

4 References

Codex (2009) Foods derived from modern biotechnology, Second Edition. Codex Alimentarius Commission, Rome. http://www.fao.org/3/a1554e/a1554e00.htm

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Richroch A, 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

Schnell J, Steele M, Bean J, et al. (2015) A comparative analysis of insertional effects in genetically engineered plants: considerations for pre-market assessments. Transgenic Res. 24(1):1-17

Attachments

A. Approved draft variation to the Australia New Zealand Food Standards Code
B. Explanatory Statement

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

Food Standards (Application A1276 – Food derived from herbicide-tolerant soybean line MON94313) Variation

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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]

Christel Leemhuis
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 A1276 – Food derived from herbicide-tolerant soybean line MON94313) 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

Schedule 26—Food produced using gene technology

[1] Subsection S26—3(4) (table item 7, column headed "*Food derived from:*")

Insert:

(s) herbicide-tolerant soybean line MON94313

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1276 – Food derived from herbicide-tolerant soybean line MON94313) Variation

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 A1276 which sought to amend the Code to permit the sale and use of food derived from a new food produced using gene technology (GM food) – soybean line MON94313. Soybean line MON94313 has been genetically modified for tolerance to the herbicides dicamba, glufosinate, 2,4-D and mesotrione. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards (Application A1276 – Food derived from herbicide-tolerant soybean line MON94313) Variation*.

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand,

Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation amending the table to subsection S26—3(4) in Schedule 26 of the Code to permit the sale and use of food derived from a new GM food – soybean line MON94313, in accordance with the Code. Soybean line MON94313 has been genetically modified for tolerance to the herbicides dicamba, glufosinate, 2,4-D, and mesotrione.

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1276 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 30 October 2023 for a six-week consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[13]. Impact analysis is no longer required to be finalised with the OIA. Prior to those changes, the OIA advised FSANZ that a Regulatory Impact Statement was not required for applications relating to GM foods - previous OIA reference number: 12065. This is because applications relating to permitting the use of GM foods that have been determined to be safe are considered to be minor and deregulatory in nature, as the use of the GM food will be voluntary if the draft variation related to the application is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

6. 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 44 of the *Legislation Act 2003*.

7. Variation

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1276 – Food derived from herbicide-tolerant soybean line MON94313) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation will commence on the date of gazettal of the instrument.

Item [1] of the Schedule to the variation amends Schedule 26 by inserting, in alphabetical

[13] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

order, new paragraph ‘(s)’ into the column headed ‘*Food derived from:*’ for item 7 of the table to subsection S26—3(4) of the Code. Item 7 of this table is headed ‘Soybean’.

The new paragraph (s) refers to ‘herbicide-tolerant soybean line MON94313’.

The effect of this amendment is to permit the sale and use of food derived from soybean line MON94313 in accordance with the Code.