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Approval report – Application A1264

Food derived from drought-tolerant and herbicide-tolerant soybean line IND-00410-5

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Bioceres Crop Solutions 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 IND-00410-5. This soybean line has been genetically modified for tolerance to drought and the herbicide glufosinate.

On 21 April 2023, FSANZ sought [submissions](#) on a draft variation to Schedule 26 and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 13 September 2023. The Food Ministers' Meeting¹ was notified of FSANZ's decision on 25 September 2023.

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

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 Support Document 1 - Safety Assessment Report

² <https://www.foodstandards.gov.au/code/applications/Pages/A1264---Food-derived-from-drought-tolerant-and-herbicide-tolerant-soybean-line-IND-00410-5.aspx>

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Bioceres Crop Solutions seeking to amend 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 IND-00410-5. Soybean line IND-00410-5 has been genetically modified for tolerance to drought and the herbicide glufosinate.

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 central part of considering an application.

The safety assessment of soybean line IND-00410-5 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 soybean line IND-00410-5 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 IND-00410-5 in accordance with the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 21 April 2023. Two submissions were received in the six-week consultation period. FSANZ has had regard to both submissions (see Section 2.1).

For reasons summarised in this report, FSANZ has decided to approve the draft variation proposed at the call for submissions with one amendment to correct a typographical error. The approved draft variation will amend Schedule 26 of the Code to include a new item 7(r) in the table to subsection S26—3(4) containing a reference to 'drought-tolerant and herbicide-tolerant soybean line IND-00410-5'. The effect of the approved draft variation will be to permit the use and sale of food derived from this soybean line in accordance with the Code.

1 Introduction

1.1 The applicant

Bioceres Crop Solutions is an integrated technology provider that develops a range of products to improve crop productivity for the agriculture sector.

1.2 The application

Application A1264 was submitted on 10 January 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 IND-00410-5. Soybean line IND-00410-5 has been genetically modified for tolerance to drought and the herbicide glufosinate.

Drought tolerance is conferred by the expression of the novel transcription factor HaHB4, encoded by the *HaHB4* gene from sunflower. The novel transcription factor regulates gene transcription in the soybean in response to environmental stressors such as drought. The HaHB4 protein has previously been assessed by FSANZ in [Application A1232](#)³.

Tolerance to glufosinate is achieved through expression of the enzyme phosphinothricin acetyltransferase (PAT), encoded by the *bar* gene from the soil bacterium *Streptomyces hygroscopicus*. The PAT protein has been assessed by FSANZ in numerous applications, most recently in Application A1232.

Soybean line IND-00410-5 will be cultivated in other countries such as Canada and the United States. The applicant has not stated any intent to cultivate IND-00410-5 in either Australia or New Zealand. It is therefore anticipated food products derived from IND-00410-5 may enter the Australian and New Zealand food supplies via imports from major soybean-producing countries. Imports may include soybean oil, milk, flour, meal, protein isolates and processed products.

Food from soybean line IND-00410-5 containing viable seeds would require prior assessment and approval by the Gene Technology Regulator (GTR)⁴ in Australia and the Environmental Protection Authority (EPA)⁵ in New Zealand.

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

³ <https://www.foodstandards.gov.au/code/applications/Pages/A1232-%20Food%20derived%20from%20drought-tolerant%20and%20herbicide-tolerant%20wheat%20line%20IND-00412-7%E2%80%99.aspx>

⁴ 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*.

⁵ The EPA implements and enforces the *Hazardous Substances and New Organisms (HSNO) Act 1996*.

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*⁶. 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 is considered to have an altered characteristic as described above), 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.

⁶ 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*).

1.6 Decision

The draft variation as proposed following assessment was approved with one amendment to correct a typographical error. 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 findings

2.1 Summary of issues / comments raised in submissions

FSANZ called for submissions on a proposed draft variation on 21 April 2023. The consultation period was six weeks.

A total of two submissions were received. Both submissions supported the proposed draft variation to Schedule 26. These submissions were from:

- New Zealand Food Safety (NZFS)
- New Zealand Food & Grocery Council (NZFGC).

One comment was raised related to the reported phytic acid level in soybean line IND-00410-5. A response to this comment is provided in Table 1.

Table 1: Comment provided during the public consultation

Comment	Raised by	FSANZ response
Although the mean level of phytic acid (1.67%) found in the soybean line IND-00410-5 falls just within the upper limit of the reference mean range of the commercial non-genetically modified soybean (1.69%), the soybean line IND-00410-5 expresses a range of phytic acid which exceeds the maximum and minimum limits of the publicly available range for phytic acid in soybean	NZFS	<p>The reported range for the non-GM commercial reference varieties (0.54 – 1.69 % DW⁷) represents the minimum and maximum mean range recorded for these varieties. FSANZ expects the minimum and maximum range for these non-GM reference varieties to be much broader and better compare with the IND-00410-5 range (0.62 – 3.09 % DW).</p> <p>FSANZ notes that the publicly available range in the application dossier (0.63 – 1.96 % DW) is derived from a 2017 AFSI database. Since then, a mean level of 3.48%⁸ DW of phytic acid content in soybean has been reported (Punjabi et al. 2018), thereby broadening the publicly available range and exceeding the maximum range value measured for phytic acid in soybean line IND-00410-5.</p> <p>The minimum value measured for phytic acid in soybean line IND-00410-5 (0.62 % DW) is within the minimum mean value (0.54 % DW) recorded for non-GM commercial reference varieties grown under the same agronomic and environmental conditions.</p> <p>Therefore, FSANZ considers the phytic acid range observed in IND-00410-5 to be consistent with normal biological variability found in non-GM soybean varieties and does not raise any safety concerns.</p>

⁷ Dry Weight

⁸ data converted from g/100g to % DW

2.2 Safety assessment

The safety assessment of soybean line IND-00410-5 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 IND00410-5 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 IND-00410-5, or any risks to animals that may consume feed derived from soybean line IND-00410-5. Permission to cultivate soybean line IND-00410-5 or to import viable seeds into Australia or New Zealand would require separate regulatory assessment and approval by the Gene Technology Regulator (GTR) in Australia and by the Environmental Protection Authority (EPA) 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 IND-00410-5 is considered to be as safe for human consumption as food derived from non-GM soybean varieties.

2.3 Risk management

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

Following the call for submissions and 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 with one amendment to correct a typographical error (see Attachment A).

2.3.1 Regulatory approval

Soybean line IND-00410-5 is a GM food for Code purposes as it is developed from 'an organism which has been modified using gene technology'. The approved draft variation lists soybean line IND-00410-5 in the table to subsection S26—3(4). Following gazettal, this will provide permission for the sale and use of food derived from soybean line IND-00410-5 as a GM food in accordance with the Code.

Food derived from soybean line IND-00410-5 may enter the Australian and New Zealand food supply as imported food products. These may include soybean oil, milk, flour, meal, protein isolates and processed products. Food from soybean line IND-00410-5 containing viable seeds would require 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 IND-00410-5 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), 2(A) 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 IND-00410-5 does not have altered characteristics (see section 5.4 and 6 of SD1).

Refined products from soybean line IND-00410-5 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 IND-00410-5 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'.

Where required, the label statement 'genetically 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-Committee⁹ 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 for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR¹⁰-based detection method. This sequence information was supplied by the applicant for A1264.

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 21 April 2023 and 07 June 2023. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social

⁹ Now known as the Implementation Subcommittee for Food Regulation.

¹⁰ Polymerase Chain Reaction.

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 this application. Every submission was 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 Application A1264, including submissions received, are available on the [FSANZ website](#)¹¹.

The draft variation was considered for approval by the FSANZ Board having regard to 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 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 Impact Analysis¹² granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting new GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new GM foods is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

However FSANZ 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 the costs and benefits of permitting the sale and use of food derived from soybean line IND-00410-5.

FSANZ is of the view that no other realistic food regulatory measures exist. The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo by permitting the sale and use of food derived from soybean line IND-00410-5.

Costs and benefits of permitting the sale and use of food derived from soybean line IND-00410-5

The sale and use of foods derived from soybean line IND-00410-5 would be permitted under

¹¹ <https://www.foodstandards.gov.au/code/applications/Pages/A1264---Food-derived-from-drought-tolerant-and-herbicide-tolerant-soybean-line-IND-00410-5.aspx>

¹² Formerly known as the Office of Best Practice Regulation (OBPR).

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 IND-00410-5, labelling would be required to enable informed choice.

Due to the voluntary nature of the permission, industry would only use foods derived from soybean line IND-00410-5 where they believe a net benefit exists for them.

Part of any cost savings to industry may be passed onto consumers. Consumers may also have increased choice and a more reliable supply of foods derived from soybean in general, given soybean line IND-00410-5 is being marketed as more tolerant to droughts and extreme temperatures and tolerant to the herbicide glufosinate.

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 IND-00410-5, 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 a food regulatory measure developed or varied as a result of the application.

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

The applicant has submitted applications for regulatory approval of soybean line IND-00410-5 to other countries, as listed in Table 2.

Table 2: List of countries to whom applications for regulatory approval of soybean line IND-00410-5 have been submitted

Country	Agency	Type of approval sought	Status
Argentina	Ministerio de Ganadería Agricultura y Pesca (MAGyP)	Food, Feed and Cultivation/Production	Approved
Uruguay	Ministerio de Ganadería, Agricultura y Pesca (GNBio)	Food, Feed and Cultivation/Production	Submitted
United States	Food and Drug Administration (FDA)	Food and feed	Approved
	United States Department of Agriculture (USDA)	Determination of non-regulated status	
China	Ministry of Agriculture and Rural Affairs (MARA)	Food and feed	Approved

Brazil	Comissão Técnica Nacional de Biossegurança (CTNBio)	Food, Feed and Cultivation/Production	Approved
Paraguay	The National Commission of Agricultural and Forestry Biosafety (CONBIO)	Food, Feed and Cultivation/Production	Approved
Bolivia	Ministerio de Medio Ambiente y Agua (MMAyA)	Food, Feed and Cultivation/Production	Submitted
Canada	Canadian Food Inspection Agency (CFIA) – Plant Biosafety Office (PBO)	Cultivation/Production	Approved
	Health Canada	Food	
	Canadian Food Inspection Agency (CFIA) – Animal Feed Division (AFD)	Feed	
India	Genetic Engineering Appraisal Committee (GEAC)	Food and feed	Submitted
European Union	European Food Safety Authority (EFSA)	Food and feed	Submitted
Malaysia	Department of Biosafety (DoB)	Food and feed	Submitted
Indonesia	Ministry of Agriculture (MoA)	Feed	Submitted
	National Agency of Drug and Food Control (BPOM)	Food	Submitted
South Africa	Department of Agriculture, Land Reform and Rural Development (DALRRD)	Food and feed	Approved
Thailand	Food and Drug Administration (FDA)	Food	Submitted
Columbia	Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)	Food	Submitted
	Instituto Colombiano Agropecuario (ICA)	Feed	Submitted

Cultivation of soybean line IND-00410-5 in or importation of viable seeds into Australia or New Zealand would require independent assessment and approval by the GTR and EPA, respectively.

Further 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 IND-00410-5. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from soybean line IND-00410-5 is considered to be 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 IND-00410-5 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 IND-00410-5 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**

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. Soybean line IND-00410-5 is a new food crop designed to provide growers with an additional tool to maintain crop productivity during conditions of low water availability.

- **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.

6 References

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

Punjabi M, Bharadvaja N, Jolly M, Dahuja A, Sachdev A (2018) Development and Evaluation of Low Phytic Acid Soybean by siRNA Triggered Seed Specific Silencing of Inositol Polyphosphate 6-/3-/5-Kinase Gene. *Frontiers in Plant Science*. 9

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 A1264 – Food derived from drought-tolerant and herbicide-tolerant soybean line IND-00410-5) 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]

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 A1264 – Food derived from drought-tolerant and herbicide-tolerant soybean line IND-00410-5) 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:

(r) drought-tolerant and herbicide-tolerant soybean line IND-00410-5

Attachment B Explanatory statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1264 – Food derived from drought-tolerant and herbicide-tolerant soybean line IND-00410-5) 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 A1264 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 IND-00410-5. Soybean line IND-00410-5 has been genetically modified for tolerance to drought and the herbicide glufosinate. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1264 – Food derived from drought-tolerant and herbicide-tolerant soybean line IND-00410-5) 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 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 sunset 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 sunset 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 sunset 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 IND-00410-5, in accordance with the Code. Soybean line IND-00410-5 has been genetically modified for tolerance to drought and the herbicide glufosinate.

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 A1264 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 21 April 2023 for a 6-week consultation period.

The Office of Impact Analysis¹³ granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new GM foods is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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 provides that the name of the variation is the *Food Standards (Application A1264 – Food derived from drought-tolerant and herbicide-tolerant soybean line IND-00410-5) Variation*.

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

Clause 3 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 of the Code by inserting new paragraph (r) into the column headed '**Food derived from:**' for item 7 of the table to subsection S26—3(4) in alphabetical order.

Item 7 of the table refers to 'Soybean'.

The new paragraph (r) refers to 'drought-tolerant and herbicide-tolerant soybean line IND-00410-5'.

¹³ Formerly known as the Office of Best Practice Regulation (OBPR).

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