6 May 2022
199-22

Approval report – Application A1232

Food derived from drought-tolerant wheat line IND-00412-7

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Trigall Genetics seeking to permit the sale and use of food derived from a new food produced using gene technology: wheat line IND-00412-7. This wheat line has been genetically modified for drought and herbicide tolerance (glufosinate).

On 6 December 2021, FSANZ sought submissions on a draft variation to Schedule 26 of the Australia New Zealand Food Standards Code and published an associated report. FSANZ received eight submissions.

FSANZ approved the draft variation on 27 April 2022.The Food Ministers' Meeting (formerly the Australia and New Zealand Ministerial Forum on Food Regulation) was notified of FSANZ's decision on 6 May 2022.

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

Table of contents

Supporting document

The following documents which informed the assessment of this application are available on the FSANZ website[1]:

SD1 Supporting document 1 (safety assessment)

[1] 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

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Trigall Genetics seeking 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): wheat line IND-00412-7. Wheat line IND-00412-7 has been genetically modified for tolerance to drought and to 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* (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 wheat line IND-00412-7 is in Supporting Document 1 (SD1). No public health and safety concerns have been identified. Based on the data provided and other information, food derived from wheat line IND-00412-7 is considered to be as safe for human consumption as food derived from conventional non-GM wheat cultivars.

Existing labelling requirements for GM food will apply to food derived from wheat line IND-00412-7 in accordance with the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 6 December 2022. Eight submissions were received. FSANZ has had regard to these submissions (see Section 2.1).

For the reasons summarised in this report, FSANZ has decided to approve the draft variation proposed following assessment without change. The approved draft variation amends Schedule 26 of the Code by inserting a reference to ‘drought-tolerant and herbicide-tolerant wheat line IND-00412-7’ in the table to subsection S26—3(4). The effect of the approved draft variation is to permit the use and sale of food derived from this wheat line in accordance with the Code.

1 Introduction

1.1 The applicant

Trigall Genetics is a Uruguay-based joint venture between Bioceres Crop Solutions and Florimond Desprez.

1.2 The application

Application A1232 was submitted on 8 June 2021. It seeks approval for the sale and use of food derived from a new food produced using gene technology (GM food): wheat line IND-00412-7. Wheat line IND-00412-7 has been genetically modified for tolerance to drought and to 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 wheat in response to environmental stressors such as drought. The HaHB4 protein has not previously been assessed by Food Standards Australia New Zealand (FSANZ).

Tolerance to glufosinate ammonium is achieved through expression of the enzyme phosphinothricin acetyltransferase (PAT), encode by the *bar* gene from the soil bacterium *Streptomyces hygroscopicus.* The PAT protein has previously been assessed by FSANZ.

Food derived from wheat line IND-00412-7 may enter the Australian and New Zealand food supply as imported food products. These may include flour, bread, pasta, biscuits and other baked products. Permission to cultivate wheat line IND-00412-7 or to import viable seeds into Australia or New Zealand would require prior regulatory assessment and approval by the Gene Technology Regulator (GTR)[2] in Australia and the Environmental Protection Authority (EPA)[3] in New Zealand. No such permissions currently exist.

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 Australia New Zealand Food Standards Code (the Code) sets out the permission and conditions for the 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 certain exceptions listed below, section 1.5.2—4 requires food to be labelled as 'genetically modified' where novel DNA and/or novel protein remains present in the final food.

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

[2] 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.*

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

produced using gene technology.

The requirement to label as 'genetically modified' applies to foods for sale that consist of, or have as an ingredient (including food additives and processing aids), food that is a *genetically modified food*[4]. 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).

The labelling requirement in section 1.5.2—4 does not apply if the genetically modified 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 final food;
- is a flavouring substance present in the food in a concentration of no more than 1g/kg (0.1%); or
- is unintentionally present in the food in an amount of no more than 10g/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 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)).

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* (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

[4] 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*).

approved draft 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 raised in submissions

FSANZ called for submissions on a proposed draft variation on 6 December 2021. The consultation period was eight weeks.

A total of eight submissions were received. Submissions in support of the proposed draft variation to Schedule 26 were received from:

- Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions
- New Zealand Food Safety (NZFS)
- Grain Producers South Australia Ltd (GPSA)
- Murdoch University, WA State Agricultural Biotechnology Centre
- one private individual

NZFS and Murdoch University stated their agreement with FSANZ's safety assessment conclusions (Section 2.2) that no potential public health and safety concerns have been identified and that food from wheat line IND-00412-7 is safe for human consumption. Murdoch University also noted that wheat line IND-00412-7 demonstrates up to a 20% increase in yield under circumstances of water stress, which is of great interest to countries where drought is a limiting factor for agricultural production. The GPSA stated that GM plant varieties such as wheat line IND-00412-7 have the potential to increase sustainability and profitability by reducing impacts from environmental stressors, as well as increasing yield potential and nutritional value.

Submissions opposing the proposed draft variation were received from:

- Allied Pinnacle Pty Ltd (Australia)
- Champion Flour Milling Ltd
- George Weston Foods Limited

Responses to issues raised in submissions are provided in Table 1.

Some submissions raised issues that are not part of FSANZ's responsibility. For example issues related to wheat cultivation in Australia and New Zealand, farming practices, the environment, trade and general GM issues not directly related to FSANZ's food safety assessment. Where possible, links to other sources of information regarding these issues have been provided in FSANZ's responses in Table 1.

Table 1: Summary of issues raised or implied by submissions

Issue	Raised by	FSANZ response
FSANZ's assessment was not independent.	Allied Pinnacle, Champion Flour Milling	FSANZ is an independent statutory agency established by the *Food Standards Australia New Zealand Act 1991*. FSANZ assessed the application independently in accordance with that Act. FSANZ's assessment relied on a data package supplied by the applicant that consisted of quality assured raw experimental data for the GM food. The data package supplied by the applicant complied with the FSANZ data requirements as set out in the FSANZ Application Handbook. FSANZ did not accept the data package at face value. FSANZ made its own assessment of the data to reach an independent conclusion about the safety of the food and did not rely on the data package alone. FSANZ's assessment also considered and relied on a range of other information from the scientific literature, other applications to FSANZ, other government agencies and the public.
Inconclusive evidence that no unintentional unknown proteins are produced in the wheat grain from broken fragments of *gus* and *bla* genes that are generated during the particle bombardment process; unintended effects and potential for allergenicity and toxicity concerns on human health.	Allied Pinnacle, Champion Flour Milling	FSANZ does not agree that the available evidence is inconclusive. For the reasons outlined in the safety assessment, no protein products from the *bla* and *gus* genes are expected in wheat line IND-00412-7 (Section 3.4.1 and Section 4 of the SD1). In the unlikely scenario that the *bla* or *gus* sequences were to be expressed, the data shows there are no allergenic or toxicity concerns for human health (Section 3.4.3 of the SD1). FSANZ notes the safety of the *bla* and *gus* genes has been assessed by FSANZ in a number of previous applications (A375, A378, A380, A383, A387, A436, A481). The presence of these genes or gene fragments does not raise any safety concerns. FSANZ notes unintended changes are not unique to GM food and occur with all forms of genetic modification including 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 changes 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).
Lack of data on any chemical residues in the food (bran or endosperm) derived from wheat line IND-00412-7; the impact of herbicide tolerance on chemical residues, human health and the environment including biodiversity has not been considered.	Allied Pinnacle, Champion Flour Milling	The GM food safety assessment does not determine the amount of herbicide residue that is allowed to be present on a GM food. This is done through a separate process that is applied to both conventionally bred (non-GM) and GM crops. Residues of agricultural and veterinary chemicals can only legally be present on food if they comply with maximum residue limits (MRLs). MRLs specify how much residue is allowed to remain in a harvested crop after the chemical has been sprayed and ensures that residue levels are kept as low as possible. The same MRL applies whether the food comes from a non-GM or GM crop.

	Regular monitoring by FSANZ of residues in ready-to-eat foods shows that residue levels are generally very low and do not pose any health concerns to consumers. Regular monitoring of residues in raw agricultural commodities is undertaken by other government agencies for compliance purposes. This monitoring shows that MRLs are very rarely exceeded. If an exceedance is found, it is reported to the relevant enforcement agency. Issues regarding the environment and biodiversity are outside the scope of FSANZ's responsibility. Please refer to the following Department of Agriculture, Water and the Environment website[5] for Australia and the Environmental Protection Authority website[6] for New Zealand.
ed Pinnacle, ampion Flour ing	FSANZ notes the issue raised by the submitter, however it is outside of FSANZ's remit[7] to consider such matters in an assessment of the safety of a GM food. The assessment of wheat line IND-00412-7 was restricted to human food safety and nutritional issues. The assessment did not address any risks to the environment that may occur as the result of growing wheat line IND-00412-7. Risks to the environment from wheat line IND-00412-7 would be assessed by the relevant authority in the country of cultivation. Please see Table 2 in this report. Cultivation of wheat line IND-00412-7 or importation of viable seeds into Australia or New Zealand would require prior regulatory assessment and approval by the GTR in Australia and the EPA in New Zealand. These assessments, which are separate from FSANZ's food safety assessments, would consider any potential risks to the environment. Additional information about herbicide-tolerance traits, weed resistance and changes in weed management measures in Australia can be found in the following report on the OGTR website[8].
ed Pinnacle, ampion Flour ing	Consumers have diverse views and perceptions in relation to the safety of GM foods[9]. While it would not be appropriate to consider such views and perceptions as part of the safety assessment, which is a scientific and evidence-based exercise, FSANZ addresses such sentiment through other aspects of the assessment and public engagement process for GM foods. For example, FSANZ has commissioned research into consumer sentiment as part of current work to revise and update the definitions for GM food under *Proposal P1055 – Definitions for gene*

chnology regulatory system, and the roles and responsibilities of elements within this system, please visit the following OGTR

		technology and new breeding techniques. As part of this research, focus groups were asked to discuss how they feel about a range of different scenarios involving gene technology. One of the scenarios tested was drought tolerant wheat[10]. The response of participants to this scenario was generally positive, with a number of participants commenting on the potential benefits in terms of improved production, sustainability, product quality and pricing, and combating the effects of climate change. Participants did however raise a number of questions around the impact on nutritional quality of the wheat, labelling and how the food would be regulated. Issues relating to nutritional quality, labelling and regulation were addressed by FSANZ's assessment of wheat line IND-00412-7.
There are risks in public understanding, engagement and communication with respect to genetic technologies / GM food. FSANZ needs to provide Australians and New Zealanders with information as to what is genetic modification, how it is used in food production, its benefits, the potential risks to heath or the environment, the regulations / FSANZ's safety assessment and how food containing GM ingredients will be labelled.	Allied Pinnacle, Champion Flour Milling	FSANZ is aware of recommendations for better and more accessible information on genetic modification and GM foods being provided to facilitate public understanding, engagement and communication in relation to genetic technologies / GM food. These were the findings of a systematic literature review undertaken by the Australian National University on behalf of FSANZ as part of work on new breeding techniques under Proposal P1055[11]. Action is being taken separately to address these findings. For example, FSANZ has started developing a range of communication material on GM foods and GM food labelling (fact sheets and videos) which are available on the FSANZ website[12]. Consumer research commissioned as part of Proposal P1055 can and will also be used to further expand and refine this information.
Unlike other permitted foods produced using gene technology in Schedule 26-3, wheat flour and food derived from genetically modified wheat will be processing into ingredients or foods for consumption, such as oils and animal feeds. This has a more significant impact on the consumer.	Allied Pinnacle, Champion Flour Milling	FSANZ recognises that wheat is a staple food for Australians and New Zealanders, with wheat flour being used in a variety of commonly eaten food products such as bread and various other baked goods. As part of the assessment of wheat line IND-00412-7, FSANZ determined such products will contain novel DNA or novel protein, and therefore the wheat ingredient will need to be labelled 'genetically modified'. FSANZ notes that most of Australia's wheat flour is locally produced, and New Zealand supplements its local wheat production primarily with imports from Australia, with very little wheat flour being imported from other countries - a fact both submitters readily acknowledge in their submissions. At this stage wheat line IND-00412-7 is only approved for growing in Argentina. The vast majority of wheat flour exports from Argentina go to Brazil and Bolivia. Based on currently available information, FSANZ anticipates the number of food products likely to

[10] Focus groups on consumers' responses to the use of New Breeding Techniques (NBTs) in food production (foodstandards.gov.au)
[11] ANU NBT Literature Review REVISION (foodstandards.gov.au)
[12] Education materials on GM foods and NBTs (foodstandards.gov.au)

		contain flour from wheat line IND-00412-7 and available for sale in Australia and New Zealand will be limited.
The compositional analysis of wheat line IND-00412-7 versus control showed statistical differences in protein, amino acid (leucine) and zinc; there would be limited food industry demand for imported wheat flour or wheat based foods with lower levels of protein or zinc.	Allied Pinnacle, Champion Flour Milling	FSANZ considered a number of constituents that are important for a compositional analysis in wheat (OECD 2003). While statistically significant differences were observed in a few constituents (protein, leucine and zinc), mean values were well within the range of natural variation typical for conventional wheat varieties. These data support the conclusion that there are no nutritionally relevant differences in the levels of key constituents in grain from IND-00412-7 compared to conventional wheat varieties (Section 5 of the SD1).
There is no benefit in supply and functionality to food manufacturers or to the Australian population nutritional status / the consumer.	Allied Pinnacle, Champion Flour Milling	The assessment of food derived from IND-00412-7 determined that, in terms of composition, there are no nutritionally relevant differences between wheat line IND-00412-7 and conventional wheat varieties. As a result flour from IND-00412-7 will be equivalent to conventional wheat in terms of functionality. The only difference will be the presence of novel DNA and novel protein in flour from IND-00412-7, which will trigger GM labelling should such flour be used as an ingredient in a food product. In terms of benefit to food manufacturers this is something that individual manufacturers will need to weigh up in deciding whether to use such ingredients. In the event a food manufacturer makes the choice to use flour from IND-00412-7 consumers will be able to exercise choice at the point of purchase. Further information about GM food labelling can be found on the FSANZ website[13]. FSANZ completed a cost benefit analysis as part of the assessment of this application. FSANZ concluded that the direct and indirect benefits that would arise from permitting the sale and use of food derived from wheat line IND-00412-7 most likely outweigh the associated costs (see section 2.5.1.1 of this report for the full analysis).
Approval of food derived from wheat line IND00412-7 could pave the way for GM wheat to be approved for commercial production or could lead to its importation as seed, posing a significant risk to the Australian and New Zealand wheat industries due to the lack of infrastructure and processes for keeping it segregated from non-GM wheat.	Allied Pinnacle, Champion Flour Milling; George Western Foods	The applicant has indicated they have no intent to import seed or apply for commercial cultivation in either Australia or New Zealand. To be imported or grown in either Australia or New Zealand, wheat line IND-00412-7 would require prior regulatory assessment and approval by the GTR in Australia and the EPA in New Zealand. These processes are separate and distinct from the food approval process, and it should not be assumed that a food approval for wheat line IND-00412-7 would automatically lead to approvals being sought for the importation of seed or its cultivation in either Australia or New Zealand. FSANZ notes the majority of GM food approvals in the Code are for crops that have never been cultivated or imported as seed in either Australia or New Zealand.
There have not been adequate peer	George Western	FSANZ is not aware that any relevant peer reviewed food consumption studies using wheat line

[13] https://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx

reviewed food consumption studies to demonstrate that no risk of harm arises for consumers.	Foods	IND-00412-7 exist. Such studies are not routinely required by FSANZ because a scientifically-informed comparative assessment of a GM food with its conventional counterpart is considered sufficient to identify any potential safety concerns. For most GM foods, food consumption studies are unlikely to contribute any further useful information.

2.2 Safety assessment

The safety assessment of wheat line IND-00412-7 is provided in Supporting Document 1 (SD1) and included the following key elements:

- a characterisation of the transferred genetic material
- characterisation of novel nucleic acids and protein in the whole food
- detailed compositional analyses
- evaluation of intended and unintended changes
- assessment of newly expressed proteins for potential allergenicity and toxicity.

In conducting the safety assessment, FSANZ considered 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 safety assessment of wheat line IND-00412-7 was restricted to human food safety and nutritional issues. 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 wheat line IND-00412-7 is considered to be as safe for human consumption as food derived from non-GM wheat cultivars.

The assessment did not address any risks to the environment that may occur as the result of growing wheat line IND-00412-7, or any risks to animals that may consume feed derived from wheat line IND-00412-7. Potential risks to the environment would be considered in the event that permission was sought to cultivate wheat line IND-00412-7 or import viable seeds into Australia or New Zealand. In this case, separate regulatory assessment would be undertaken by the GTR in Australia and by the EPA in New Zealand. Where GM crops are intended for cultivation overseas, as is the case for wheat line IND-00412-7, such risk assessments would be undertaken in the country or countries where they are to be grown (e.g. see Table 2).

2.3 Risk management

2.3.1 Regulatory approval

Wheat line IND-00412-7 is a GM food for Code purposes as it is developed from ‘an organism that has been modified using gene technology’. The approved draft variation lists wheat line IND-00412-7 in the table to subsection S26—3(4). Following gazettal, this will provide permission for the sale and use of food derived from wheat line IND-00412-7 as a GM food in accordance with the Code.

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 wheat line IND-00412-7, is required to be labelled as ‘genetically modified’ if (among other things) the GM food:

- contains novel DNA or novel protein; or
- is listed in subsections 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 wheat line IND-00412-7 does not have altered characteristics.

As noted in Section 1.2 of this report, food derived from wheat line IND-00412-7 may enter the Australian and New Zealand food supply as imported food products for sale such as flour, bread, pasta, biscuits and other baked products. These products will contain novel DNA or novel protein and the wheat ingredient will need to be labelled 'genetically modified'. The labelling requirement will not apply to highly refined foods made from this wheat (for example, ethanol) if they do not contain novel DNA or novel protein.

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, wheat flour derived from wheat line IND-00412-7 that is for retail sale will require the labelling statement. However, FSANZ notes products derived from wheat line IND-00412-7 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 a food sold to a caterer (for example, wheat flour derived from wheat line IND-00412-7 is used to make a sauce then used as an ingredient in a 'ready meal'). As such, these ingredients will not be GM foods and will not be subject to labelling requirements set out in section 1.5.2—4.

Should viable seeds be approved in Australia and/or New Zealand (see Section 1.2 of this report), future products for sale may include wheat seeds (known as 'wheat berries') which can be used in salads and cereals or, when germinated, can be consumed as sprouts or wheat grass. The requirement for the labelling statement 'genetically modified' will apply to these foods. If the food for sale was not in a package (for example, wheat grass was used as an ingredient in a juice that is made and packaged on the premises from which it is sold), the information will need to be stated in labelling that accompanies the food or is displayed in connection with the display of the food.

2.3.3 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-Committee[14] 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 A1232.

2.3.4 Trade considerations

The applicant has indicated there is no intention to apply for commercial cultivation of wheat line IND-00412-7 in Australia or New Zealand. If cultivation were sought, it would require independent assessment and approval by the GTR or EPA. Providing permission for growing and / or distribution of wheat line IND-00412-7 overseas is the responsibility of local regulatory agencies in the respective countries.

Although wheat line IND-00412-7 is not likely to be grown or sold in Australia or New Zealand, flour from IND-00412-7 may be present in imported consignments of wheat flour. In 2019, Australia and New Zealand imported approximately 29,172 and 19,712 tonnes of wheat flour, respectively (FAOSTAT 2019). While wheat line IND-00412-7 is not currently grown overseas on a commercial scale, flour from this line may in the future be present in imports to Australia and New Zealand. A permission in the Code for food derived from wheat line IND-00412-7 is necessary to facilitate trade and ensure the ongoing supply of wheat

[14] Now known as the Implementation Subcommittee for Food Regulation.

flour into Australia and New Zealand.

It should be noted that uncooked and unprocessed IND-00412-7 whole grain could not be imported into Australia or New Zealand without assessment and approval by the GTR or EPA. This is because the presence of a viable embryo means the wheat could be germinated i.e. would be regarded as a viable genetically modified organism. Imported whole grain would also need to meet biosecurity requirements in Australia and New Zealand.

World Trade Organization (WTO) obligations are covered in Section 2.4.2 of this report.

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 6 December 2021 and 31 January 2022. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media tools 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 on this application 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 A1232, including submissions received, are available on the FSANZ website[15].

2.4.2 World Trade Organization (WTO)

As members of the WTO, Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to permit food derived from wheat line IND-00412-7 is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

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.

[15] 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

2.5.1 Section 29

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:

2.5.1.1 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 (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 gene technology will be voluntary if this 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, 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 FSANZ's 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 was rejecting the application). This analysis considers permitting the sale and use of food derived from wheat line IND-00412-7.

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 could not 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 the sale and use of food derived from wheat line IND-00412-7.

Costs and benefits of permitting the sale and use of food derived from wheat line IND-00412-7

The sale and use of foods derived from wheat line IND-00412-7 would 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 wheat line IND-00412-7, labelling is 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 wheat line IND-00412-7, 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.

During the Call for Submissions, certain submitters raised concerns about human health effects, including from unintentional unknown proteins being produced in the wheat grain from wheat line IND-00412-7 and herbicide tolerance.

FSANZ's assessment is that both the wheat line IND-00412-7 itself and the possibility of unknown proteins represent very low allergen or toxicity risks to human health. Residues of agricultural and veterinary chemicals can only legally be present on food if they comply with

maximum residue limits (MRLs). MRLs specify how much residue is allowed to remain in a harvested crop after the chemical has been sprayed and ensures that residue levels are kept as low as possible. The same MRL applies whether the food comes from a non-GM or GM crop.

Two industry submitters also expressed concerns of a potential longer-term reputational risk caused by unintentional contamination of genetically modified wheat in non-GM grains, wheat, feed and food industries. They argued this may damage the "clean, green" reputation of Australia's and New Zealand's wheat industries. Given that approval to cultivate or import seed from wheat line IND-00412-7 has not yet been sought or obtained, the relatively low volume of wheat flour imports to Australia-New Zealand, and the low risk of harm from food derived from wheat line IND-00412-7, FSANZ believes that any reputational risk to industry is low.

Conclusions from cost benefit considerations

FSANZ's assessment remains that the direct and indirect benefits that would arise from permitting the sale and use of food derived from wheat line IND-00412-7, 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 the Application A1232.

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 wheat line IND-00412-7 to a number of other countries, listed in Table 2.

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

Table 2: List of countries to whom applications for regulatory approval of wheat line IND-00412-7 have been submitted

Country	Agency	Type of approval sought	Status
Argentina	Ministerio de Ganadería Agricultura y Pesca (MAGyP)	Environmental release, food & feed	Approved
Brazil	National Biosafety Commission (CTNBio)	Food & feed	Approved
Colombia	Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)	Food	Approved
	Instituto Colombiano Agropecuario (ICA)	Feed	Approved

Indonesia	National Agency of Drug and Food Control	Food	Submitted
	Ministry of Agriculture	Feed	Submitted
Paraguay	The National Commission of Agricultural and Forestry Biosafety (CONBIO)	Environmental release, food & feed	Submitted
South Africa	Department of Agriculture, Land Reform & Rural Development	Food & feed	Submitted
United States	United States Department of Agriculture (USDA)	Determination of nonregulated status	Submitted
	Food and Drug Administration (FDA)	Food & feed	Submitted
Uruguay	Ministerio de Ganadería, Agricultura y Pesca (GNBio)	Environmental release, food & feed	Submitted

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 wheat line IND-00412-7. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from wheat line IND-00412-7 is considered to be as safe for human consumption as food derived from conventional non-GM wheat cultivars.

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 wheat line IND-00412-7 in accordance with the Code to enable informed consumer choice (see Section 2.3.2 of this report). In addition, action is being taken to make information on genetic modification and GM foods more accessible to the public to facilitate better understanding, engagement and communication in relation to GM food (Table 1). For example, FSANZ has developed a number of fact sheets and videos on GM foods and GM food labelling[16].

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 of this report) addresses this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

[16] Education materials on GM foods and GM food labelling (foodstandards.gov.au)

- **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 wheat line IND-00412-7 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**

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. Wheat line IND-00412-7 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 of this report above.

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

There are no written policy guidelines.

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) 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

FSANZ (2019) Final report – Review of food derived using new breeding techniques. https://www.foodstandards.gov.au/consumer/gmfood/Documents/NBT%20Final%20report.pdf

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

OECD (2003a). Consensus document on compositional considerations for new varieties of bread wheat (Triticum aestivum): key food and feed nutrients, anti-nutrients and toxicants. ENV/JM/MONO(2003). Series on Harmonization of Regulatory Oversight in Biotechnology. Environment Directorate. Organisation for Economic Co-operation and Development. Paris

https://www.oecd.org/env/ehs/biotrack/46815206.pdf

Ricroch AE (2013) Assessment of GE food safety using '-omics' techniques and long-term animal feeding studies. N Biotechnol 30(4):349–354

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 A1232 – Food derived from drought-tolerant and herbicide-tolerant wheat line IND-00412-7) 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 A1232 – Food derived from drought-tolerant and herbicide-tolerant wheat line IND-00412-7) 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) (after table item 9)

Insert:

10	**Wheat**	(a)	drought-tolerant and herbicide-tolerant wheat line IND-00412-7

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 A1232 which seeks to permit the sale and use of food derived from a new food produced using gene technology (GM food) - wheat line IND-00412-7. Wheat line IND-00412-7 has been genetically modified for tolerance to drought and to the herbicide glufosinate. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting (formerly the Australia and New Zealand Ministerial Forum on Food Regulation)[17], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

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 Food Ministers Meeting (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.

[17] The Forum name change took effect on 21 February 2021 following a decision by Ministers.

3. Purpose

The purpose of the approved draft variation is to permit the sale and use of food derived from a new GM food - wheat line IND-00412-7, in accordance with the Code. Wheat line IND-00412-7 has been genetically modified for tolerance to drought and to 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 A1232 included one round of public consultation following an assessment and the preparation of a draft variation.

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 (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 a new GM food is deregulatory as using the food 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

Item [1] amends Schedule 26 by inserting new item 10 into the table to subsection S26—3(4).

The table to subsection S26—3(4) lists permitted GM food of plant origin.

New item 10 consists of the following entries:

- column 1 – references to '10' as the new item number and 'Wheat' as the new commodity; and
- column 2 – a reference to '(a) drought-tolerant and herbicide-tolerant wheat line IND-00412-7' as a permitted GM food.

The effect of the variation is to permit the sale and use of food derived from wheat line IND-00412-7 in accordance with the Code.