

14 February 2025
329-25

Approval report – Application A1303

Food derived from herbicide-tolerant sugar beet line KWS20-1

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Bayer CropScience Proprietary Limited 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: sugar beet line KWS20-1. This sugar beet line has been genetically modified for tolerance to the herbicides dicamba, glufosinate and glyphosate.

On 16 September 2024, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation on 5 February 2025. The Food Ministers' Meeting¹ was notified of FSANZ's decision on 14 February 2025.

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

Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD	3
1.4 REASONS FOR ACCEPTING APPLICATION	5
1.5 PROCEDURE FOR ASSESSMENT	5
1.6 DECISION	5
2 SUMMARY OF THE FINDINGS.....	5
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	5
2.2 SAFETY ASSESSMENT	6
2.3 RISK MANAGEMENT	7
2.4 RISK COMMUNICATION	8
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS.....	9
3 DRAFT VARIATION	12
4 REFERENCES.....	12
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	13
ATTACHMENT B – EXPLANATORY STATEMENT	15

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/application-a1303-food-derived-herbicide-tolerant-sugar-beet-line>

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from Bayer CropScience Proprietary Limited seeking a variation of 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): sugar beet line KWS20-1. Sugar beet line KWS20-1 has been genetically modified (GM) for tolerance to the herbicides dicamba, glufosinate and glyphosate.

As stated in section 18 of the *Food Standards Australia New Zealand Act 1991*, a primary objective of FSANZ in developing or varying a food regulatory measure is the protection of public health and safety. Accordingly, a safety assessment is a critical part of the assessment and approval process for all GM food applications.

The safety assessment for sugar beet line KWS20-1 is in Supporting Document 1. The assessment found no potential public health and safety concerns. Based on the data provided by the applicant and other information, food derived from sugar beet line KWS20-1 is considered to be as safe for human consumption as food derived from conventional non-GM sugar beet varieties.

Existing labelling requirements for GM food will apply to food derived from sugar beet line KWS20-1 in accordance with the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 16 September 2024. Six 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 paragraph (c) for item 8 in the table to subsection S26—3(4) containing a reference to 'herbicide-tolerant sugar beet line KWS20-1'. The effect of the approved draft variation will be to permit the sale and use of food derived from this sugar beet line in accordance with the Code.

1 Introduction

1.1 The applicant

Bayer CropScience Proprietary Limited is a technology provider to a number of industry sectors, including agriculture.

1.2 The application

Application A1303 was submitted on 15 May 2024. 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): sugar beet line KWS20-1. This sugar beet line has been genetically modified (GM) for tolerance to the herbicides dicamba, glufosinate and glyphosate. KWS20-1 expresses three novel substances, summarised in Table 1.

Table 1. Novel substances expressed in KWS20-1

Protein	Gene	Donor organism	Function	Previously assessed by FSANZ?
Dicamba mono-oxygenase (DMO)	<i>dmo</i>	<i>Stenotrophomonas maltophilia</i>	Dicamba tolerance	Yes 6 previous applications
Phosphinothricin acetyltransferase (PAT)	<i>pat</i>	<i>Streptomyces viridochromogenes</i>	Glufosinate tolerance	Yes 35 previous applications
CP4 EPSPS	<i>cp4 epsps</i>	<i>Agrobacterium</i> sp. strain CP4	Glyphosate tolerance	Yes 16 previous applications

1.3 The current standard

Pre-market approval

Standard 1.1.1 of the Code provides that, unless expressly permitted by the Code, a food for sale cannot be, or have as an ingredient or component, a GM food.³ Standard 1.1.2 defines what is a 'food produced using gene technology' (referred to generally as a GM food in this report) for this purpose.⁴

The above in effect requires pre-market approval of a GM food before it 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 sets out the permission and conditions for sale of a food that is, or has as an ingredient, a GM food. Permitted GM foods are listed in Schedule 26 of the Code. Standard 1.5.2 also provides a GM food that is permitted for use as a food additive by Standard 1.3.1 or as a processing aid by Standard 1.3.3 is also a permitted GM food for the purposes of

³ See paragraphs 1.1.1—10(5)(c) and 1.1.1—10(6)(g).

⁴ See definition in subsection 1.1.2—2(3).

Standard 1.5.2.

Labelling

Standard 1.1.1 requires that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Section 1.5.2—4 requires a food for sale that consists of, or has as an ingredient, a food that is a *genetically modified food* to be labelled as 'genetically modified'.⁵

A genetically modified food is a GM food that:

- contains novel DNA or novel protein; or
- is listed in subsections S26—3(2), (2A) and (3) (i.e. regardless of the presence of novel DNA or novel protein in the foods). The foods listed in these subsections 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.

Section 1.5.2—4 also provides that its labelling requirements do not apply if the genetically modified 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 and no novel DNA or novel protein from the substance remains 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%);
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient; or
- 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.

The labelling requirements imposed by section 1.5.2—4 apply to the following in accordance with Standard 1.2.1:

- a food for retail sale. In the case where a food for retail sale is not required by the Code to bear a label and is not in a package, subsections 1.2.1—9(2) and (3) require labelling information in section 1.5.2—4 to accompany the food or be displayed in connection with the display of the food; or
- a food sold to a caterer. In the case where a food sold to a caterer is not required by the Code to bear a label, section 1.2.1—13 and paragraph 1.2.1—15(f) require information in section 1.5.2—4 to be provided to the caterer with the food.

⁵ 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*).

1.4 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

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

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 16 September 2024. The consultation period was six weeks.

Six submissions were received. One submission – from New Zealand Food Safety (NZFS) – supported the proposed draft variation to Schedule 26, and did not raise any issues. The other five submissions were from private individuals and did not support the proposed draft variation. Some of these submitters raised an issue relating to KWS20-1 which is summarised in Table 2. Other submitters raised general concerns about GM foods that were not directly related to FSANZ's assessment of sugar beet line KWS20-1.

Table 2. Summary of issues

Issue	Raised by	FSANZ response (including any amendments to drafting)
Concerns about the health effects of consuming food exposed to the herbicides that KWS20-1 is tolerant to, particularly glyphosate.	Private submitters (S.C., M.F., R.K.)	<p>The presence of herbicide and herbicide metabolite residues is addressed through the maximum residue limit (MRL) setting process in Australia and New Zealand. MRLs are for all foods, regardless of whether the product or commodity is GM or non-GM.</p> <p>Food sold in Australia must not contain levels of agricultural chemical residues above the MRLs. MRLs are listed in Schedule 20 of the Code⁶. For food sold in New Zealand, MRLs are established by the Ministry for Primary Industries.</p> <p>FSANZ notes that GM plants tolerant to glufosinate and glyphosate have been in commercial use since the 1990s, while dicamba-tolerant GM crops have been in use for over a decade. The herbicide metabolites produced in both GM and non-GM plants sprayed with these herbicides are common across species and are well characterised. Further information can be found in section 4.5 of Supporting Document 1.</p> <p>Specific information about glyphosate is also available from the FSANZ website⁷.</p>

2.2 Safety assessment

The safety assessment of sugar beet line KWS20-1 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 sugar beet 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 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 previous applications.

The assessment of sugar beet line KWS20-1 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 sugar beet line KWS20-1, or any risks to animals that may consume feed derived from sugar beet line KWS20-1. Cultivation in Australia or New Zealand would require separate regulatory assessment and approval by the Gene Technology Regulator (GTR)⁸ in Australia and the Environmental Protection Authority (EPA)⁹ in New Zealand.

No potential public health and safety concerns have been identified.

⁶ www.foodstandards.gov.au/code/Pages/default.aspx

⁷ www.foodstandards.gov.au/consumer/chemicals/Glyphosate

⁸ 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*.

⁹ The EPA implements and enforces the *Hazardous Substances and New Organisms (HSNO) Act 1996*.

Based on the data provided in the present application and other available information, food derived from sugar beet line KWS20-1 is considered to be as safe for human consumption as food derived from non-GM sugar beet varieties.

2.3 Risk management

Following assessment, FSANZ decided to prepare a draft variation of the Code and called for submissions on that draft variation.

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

- 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.

Following the call of submissions and having regard to the submissions received, and for the reasons set out in this report, FSANZ has decided to approve the draft variation proposed following assessment without change (see Attachment A).

Risk management considerations for this application relating to the regulatory approval, labelling, and detection methodology are discussed below.

2.3.1 Regulatory approval

Sugar beet line KWS20-1 is a GM food for Code purposes as it is developed from 'an organism which has been modified by gene technology'¹⁰. The approved draft variation lists sugar beet line KWS20-1 in the table to subsection S26—3(4). This amendment will effectively provide permission for the sale and use of food derived from sugar beet line KWS20-1 as a GM food in accordance with the Code.

Subject to and in accordance with the draft variation, food derived from sugar beet line KWS20-1 may enter the Australian and New Zealand food supply as imported food products. These may include refined sugar (sucrose) or molasses.

Cultivation of sugar beet line KWS20-1 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 sugar beet line KWS20-1 will require labelling 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 sugar beet line KWS20-1 does not have altered characteristics (see section 5.3 of SD1).

¹⁰ **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'.

Refined products from sugar beet line KWS20-1 (such as sugar) are unlikely to contain any novel DNA or novel protein and will be unlikely to require labelling as 'genetically modified'.

Less refined products derived from sugar beet line KWS20-1 (such as molasses) that contain novel DNA or novel protein 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 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, food additive or processing aid, then the 'genetically modified' 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-Committee¹¹ 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 PCR¹²-based detection method. This sequence information was supplied by the applicant for A1303.

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 released for public comment between 16 September 2024 and 28 October 2024. 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 by FSANZ as part of the decision making process. All comments are valued and contribute to the rigour of our assessment.

Documents relating to A1303, including the submissions received, are available on the [FSANZ website](#)¹³.

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

¹¹ Now known as the Implementation Subcommittee for Food Regulation.

¹² Polymerase Chain Reaction.

¹³ <https://www.foodstandards.gov.au/food-standards-code/applications/application-a1303-food-derived-herbicide-tolerant-sugar-beet-line>

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 Analysis (OIA).¹⁴ 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 the applications relating to GM foods (OIA Reference: **OIA23-06225**). 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 their use will be voluntary if the application is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

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

The purpose of this consideration is to determine if the community, government or industry as a whole is likely to benefit, on balance, from a move from the status quo, where the status quo is rejecting the application. This analysis considers permitting the sale and use of food derived from herbicide-tolerant sugar beet line KWS20-1.

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 sugar beet line KWS20-1.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below.

Costs and benefits of permitting the sale and use of food derived from sugar beet line KWS20-1

Food derived from sugar beet line KWS20-1 may enter the Australian and New Zealand food supply as imported food products. These may include refined sugar (sucrose) or molasses.

The sale and use of foods derived from sugar beet line KWS20-1 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 sugar beet line KWS20-1, labelling would be required to assist consumers wishing to avoid these products.

Due to the voluntary nature of the permission, manufacturers and retailers will only engage with foods derived from sugar beet line KWS20-1 where they believe a net benefit exists for

¹⁴ [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](https://www.pmc.gov.au/regulatory-impact-analysis-guide-for-ministers-meetings-and-national-standard-setting-bodies)

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 sugar beet line KWS20-1 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

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

The applicant has submitted applications for regulatory approval of sugar beet line KWS20-1 to other countries, listed in Table 3.

Table 3. List of countries to whom applications for regulatory approval of KWS20-1 have been submitted

Country	Authority	Type of approval sought	Status
Canada	Health Canada (HC)	Food	Approved
	Canadian Food Inspection Agency (CFIA)	Feed and Environment	Approved
United States	Food and Drug Administration (FDA)	Food and Feed	Submitted
	United States Department of Agriculture (USDA)	Determination of nonregulated status	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 sugar beet line KWS20-1. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from sugar beet line KWS20-1 is as safe for human consumption as food derived from other conventional non-GM sugar beet lines.

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 sugar beet line KWS20-1 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) satisfies 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 sugar beet line KWS20-1 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. Sugar beet line KWS20-1 is a new food crop designed for tolerance to the herbicides dicamba, glufosinate and glyphosate.

- **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) 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>

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 A1303 – Food derived from herbicide-tolerant sugar beet line KWS20-1) 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 A1303 – Food derived from herbicide-tolerant sugar beet line KWS20-1) 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 8, column headed “*Food derived from:*”)

Insert:

(c) herbicide-tolerant sugar beet line KWS20-1

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1303 – Food derived from herbicide-tolerant sugar beet line KWS20-1) 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 A1303 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) – sugar beet line KWS20-1. Sugar beet line KWS20-1 has been genetically modified for tolerance to the herbicides dicamba, glufosinate and glyphosate. The Authority considered the application in accordance with Division 1 of Part 3 and approved a draft variation - the *Food Standards (Application A1303 – Food derived from herbicide-tolerant sugar beet line KWS20-1) 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 sugar beet line KWS20-1, in accordance with the Code. Sugar beet line KWS20-1 has been genetically modified for tolerance to the herbicides dicamba, glufosinate and glyphosate.

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 A1303 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 16 September 2024 for a six-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA).¹⁵ 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 (updated OIA reference: **OIA23-06225**). 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 A1303 – Food derived from herbicide-tolerant sugar beet line KWS20-1) 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

¹⁵<https://oia.pmc.gov.au/resources/guidance-impact-analysis/regulatory-impact-analysis-guide-ministers-meetings-and-national>

the instrument.

Item [1] of the Schedule to the variation amends Schedule 26 of the Code by inserting, in alphabetical order, a new paragraph '(c)' into the column headed '*Food derived from:*' for item 8 of the table to subsection S26—3(4) of the Code. Item 8 of this table is headed 'Sugarbeet'.

The new paragraph (c) refers to 'herbicide-tolerant sugar beet line KWS20-1'.

The effect of the variation is to permit the sale and use of food derived from sugar beet line KWS20-1 in accordance with the Code.