16 February 2024
281-24

Approval report – Application A1278

Beta-Fructofuranosidase from GM *Trichoderma reesei* as a processing aid

Food Standards Australia New Zealand (FSANZ) has assessed an application made by AB Enzymes GmbH to amend the Australia New Zealand Food Standards Code to permit beta-fructofuranosidase from a genetically modified strain of *Trichoderma reesei* to be used as a processing aid in the production of short-chain fructooligosaccharides, and to produce a reduction in sugar levels in treated fruit and vegetable products.

On 10 October 2023, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 2 February 2024. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 16 February 2024.

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

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

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Supporting document

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

SD1 Risk and technical assessment report (at approval)

Executive summary

AB Enzymes GmbH submitted an application to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme beta-fructofuranosidase (EC 3.2.1.26) as a processing aid. The enzyme is sourced from a genetically modified (GM) strain of *Trichoderma reesei* containing the beta-fructofuranosidase gene from *Aspergillus niger*.

Beta-fructofuranosidase is used for the production of short-chain fructooligosaccharides (scFOS) and to produce a reduction in sugar (sucrose) levels in treated fruit and vegetable products. The enzyme performs its technological purpose in the quantity and form proposed during the production process and does not perform a technological purpose in the food for sale. It therefore functions as a processing aid for the purposes of the Code.

Evidence has been provided to show that the enzyme meets relevant international purity specifications in the Code.

No public health and safety concerns were identified in the assessment of beta-fructofuranosidase produced by GM *T. reesei* under the proposed use conditions. *T. reesei* has a long history of safe use as a production microorganism of enzyme processing aids, including several that are already permitted in the Code. The production organism is neither pathogenic nor toxigenic. Analysis of the modified production strain confirmed the presence and stability of the inserted DNA. Bioinformatics analysis indicated that the produced beta-fructofuranosidase does not have substantial homology with known toxins or food allergens.

Based on the reviewed data, it is concluded that in the absence of any identifiable hazard, an acceptable daily intake ‘not specified’ is appropriate.

Following assessment and the preparation of a draft variation to the Code, FSANZ called for submissions regarding the draft variation from 10 October 2023 to 21 November 2023. FSANZ received two submissions, which supported the draft variation and did not raise any issues.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved the draft variation to the Code proposed at the call for submissions with amendments to correct formatting. The approved draft variation will amend the table to subsection S18—9(3) by adding the enzyme beta-fructofuranosidase (EC 4.2.1.26) sourced from *T. reesei,* containing the beta-fructofuranosidase gene from *A. niger* to the list of permitted processing aids for specific technological purposes in that table. The permitted technological purpose of this enzyme as a processing aid will be for the production of scFOS and to produce a reduction in sugar (sucrose) levels in treated fruit and vegetable products. The maximum permitted level, or amount of the enzyme that may be present in the food, must be an amount consistent with Good Manufacturing Practice.

1 Introduction

1.1 The applicant

The applicant is AB Enzymes GmbH, a biotechnology company that develops, manufactures and supplies enzymes preparations for various uses including food processing.

1.2 The application

The purpose of the application was to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme beta-fructofuranosidase sourced from a genetically modified (GM) strain of *Trichoderma reesei* containing the beta-fructofuranosidase gene from *Aspergillus niger*. The enzyme is proposed to be permitted as a processing aid for the production of short-chain fructooligosaccharides (scFOS) and to produce a reduction in sugar (sucrose) levels in treated fruit and vegetable products.

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

1.3.1 Permitted use

Paragraph 1.1.1—10(6)(c) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance used as a processing aid unless that substance's use as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance used as a processing aid in relation to a food is a substance used during the course of processing that meets all of the following conditions:

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale, and
- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at Good Manufacturing Practice (GMP).

Standard 1.3.3 and Schedule 18 of the Code list permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. The table to subsection S18—9(3) lists those substances, including enzymes derived from particular sources, that are permitted to be used as processing aids for specific technological purposes in relation to:

- if a food is specified—that food; or
- if no food is specified—any food.

Additionally, paragraph 1.3.3—11(c) specifies that the substance may only be used as a processing aid if it is not present in the food at a level greater than the maximum permitted level for that substance indicated in the table to section S18—9.

Paragraph 1.1.1—10(6)(g) requires that the presence as an ingredient or component in a food for sale of a food produced using gene technology must be expressly permitted by the

Code. Paragraph 1.5.2—3(b) provides that permission in the Code for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

The enzyme from specific microbial sources, which is permitted to be used as a processing aid, is listed in the table to subclause S18—4(5) (see below). It is noted that the name of the enzyme uses the Greek symbol (β) rather than being spelt out as beta.

Permitted enzymes (section 1.3.3—6)—Enzymes of microbial origin

Enzyme	***Source***
β-Fructofuranosidase (EC 3.2.1.26)	*Aspergillus fijiensis* ATCC 20611 *Aspergillus niger* *Saccharomyces cerevisiae*

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code.

Subsection S3—2(1) of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO/WHO JECFA Monographs 26 (2021)), which explicitly contains the specification for enzyme preparations in the earlier FAO/WHO (2006) document. It also references the United States Pharmacopeial Convention Food Chemicals Codex, 13th edition (FCC 2022). Both include specifications for enzyme preparations used in food processing.

1.3.3 Labelling requirements

Subsection 1.1.1—10(8) provides that food for sale must comply with all relevant labelling requirements in the Code.

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

Section 1.5.2—4 of the Code requires a food for sale that consists of a *genetically modified food*[2] (GM food) or has a GM food as an ingredient to be labelled as 'genetically modified', unless an exemption applies. The statement 'genetically modified' must be made in conjunction with the name of the GM food. If the GM food is used as a processing aid, this statement may be included in the statement of ingredients. 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.

1.4 International standards

In developing food regulatory measures, Food Standards Australia New Zealand (FSANZ) must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). There is no Codex Alimentarius 'general standard'

[2] Section 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*).

for enzymes, however as noted above there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

In addition, there is a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010), which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP.

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Australia New Zealand Food Standards Act* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application was assessed under the General Procedure.

1.7 Decision

The draft variation as proposed following assessment was approved with amendments to correct formatting. The approved draft variation takes effect on 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 the draft variation to the Code from 10 October 2023 to 21 November 2023. Two submissions were received during the consultation process. They were both supportive and did not raise any issues with the application.

2.2 Risk assessment

FSANZ conducted a risk assessment related to this application which is provided at Supporting Document 1 (SD1). The summary of this assessment is provided below.

The proposed use of this beta-fructofuranosidase as a processing aid is consistent with its known technological function. Beta-fructofuranosidase performs its technological purpose during the production of the nominated foods and is not performing a technological purpose in the food for sale. It is therefore functioning as a processing aid for the purposes of the Code.

There are relevant identity and purity specifications for the enzyme in the Code, and the applicant provided evidence that the enzyme meets these specifications.

T. reesei has a long history of safe use as a production microorganism of enzyme processing aids, including several that are already permitted in the Code. The production organism is

neither pathogenic nor toxigenic. Analysis of the genetically modified production strain confirmed the presence and stability of the inserted DNA.

Bioinformatics analysis found no significant homology of the beta-fructofuranosidase enzyme itself with known toxins or food allergens. Studies with another enzyme, phytase, from a production strain within the same safe strain lineage as that used to produce beta-fructofuranosidase, found no evidence of genotoxicity *in vitro* or *in vivo* and no adverse effects in a 90-day oral toxicity study in rats. These findings confirm the safety of the beta-fructofuranosidase production strain. The no observed adverse effect level (NOAEL) in this study was 1000 mg total organic solids (TOS)/kg body weight (bw)/day, the highest dose tested.

The theoretical maximum daily intake (TMDI) of the TOS from the beta-fructofuranosidase preparation was calculated to be 1.05 mg TOS/kg bw. A comparison of the NOAEL and the TMDI results in a Margin of Exposure (MOE) of approximately 1000.

Based on the reviewed data it is concluded that in the absence of any identifiable hazard, an acceptable daily intake (ADI) 'not specified' is appropriate.

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.

The conclusions from the risk and technical assessment were that the proposed use of the enzyme is technologically justified and there were no safety concerns associated with its proposed use.

FSANZ therefore considered it appropriate to prepare a draft variation to the Code to permit the use of beta-fructofuranosidase sourced from GM *T. reesei* containing the beta-fructofuranosidase gene from *A. niger* as a processing aid for a specific technological purpose. The permitted technological purpose is for use in the production of scFOS and to produce a reduction in sugar (sucrose) levels in treated fruit and vegetable products. This permission would be subject to the condition that the maximum permitted level or amount of enzyme that may be present in the food must be an amount consistent with GMP. FSANZ called for submissions on the draft variation.

Following the call for submissions and having regard to the submissions received, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed at the call for submissions with amendments to correct formatting.

Other risk management considerations for this application were related to the enzyme and source microorganism nomenclature, specifications and labelling. These are discussed below.

2.3.1 Regulatory approval

As stated above, FSANZ has approved an amended draft variation to permit the use of the enzyme as a processing aid in the production of scFOS and to produce a reduction in sugar (sucrose) levels in treated fruit and vegetable products.

The express permission for the enzyme to be used as a processing aid also provides the permission for its potential presence in food for sale as a food produced using gene

technology (see section 1.3.3 above). The enzyme is a food produced using gene technology for Code purposes as it is derived from 'an organism which has been modified by gene technology' (see subsection 1.1.2—2(3) of the Code) [3].

2.3.2 Enzyme nomenclature, source microorganism nomenclature and specifications

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB) uses the 'accepted name' β-fructofuranosidase (IUBMB 2023) for the enzyme numbered EC 3.2.1.26. This is the name used in the draft variation and the name used in existing permissions in Schedule 18 (subsection S18—4(5)). It is noted that the written identifier 'beta' is used in preference to the Greek symbol β in this report as symbols are not always readable on certain media platforms.

Nomenclature for the host and gene donor organisms – *T. reesei* and *A. niger* respectively – is in accordance with accepted international norms for taxonomy and are used in nomenclature of source microorganisms for permissions of different enzymes within Schedule 18.

There are relevant identity and purity specifications in primary sources of specifications listed in Schedule 3 for enzyme preparations used in food processing, namely the JECFA Combined Compendium of Food Additive Specifications and the United States Pharmacopeial Convention Food Chemicals Codex (refer to section 1.3.2 above).

2.3.3 Labelling requirements

The labelling provisions in the Code will apply to foods for sale that are manufactured using this processing aid (see section 1.3.3 above).

2.3.4 Risk management conclusion

The risk management conclusion was to permit the enzyme beta-fructofuranosidase (EC 3.2.1.26) from GM *T. reesei* containing the beta-fructofuranosidase gene from *A. niger* as a processing aid for a specific technological purpose. The permitted technological purposes are for use in the production of scFOS and to produce a reduction in sugar (sucrose) levels in treated fruit and vegetable products. The enzyme will be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The maximum permitted level or amount of the enzyme that may be present in the food would have to be an amount consistent with GMP. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code will provide permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media channels and Food Standards News.

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

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on the draft variation.

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 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)[4]. Impact analysis (including Regulatory Impact Statements, or RISs) is no longer required to be finalised with the OIA.

Prior to these changes, the OIA advised FSANZ that a RIS was not required for applications relating to processing aids and GM foods. This is because applications relating to permitting the use of processing aids and GM foods that have been determined to be safe are minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved.[5] Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

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

The purpose of this consideration was to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo, where the status quo is rejecting the application. This analysis considered permitting the use of beta-fructofuranosidase from GM *T. reesei* as a processing aid for specific technological purposes. The permitted technological purposes are for use in the production of scFOS and to produce a reduction in sugar (sucrose) levels in treated fruit and vegetable products.

The consideration of the costs and benefits in this section was 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 sought to highlight the potential positives and negatives of moving away from the status quo by permitting the use of this processing aid.

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

[4] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)
[5] Refer to the list of carve-outs on the Office of Impact Analysis website.

Costs and benefits of permitting the use of this enzyme as a processing aid

Industry
Industry may benefit from a number of improvements and efficiencies from the use of this enzyme. Due to the voluntary nature of the permission, industry will only use the enzyme as proposed where they believe a net benefit exists for them in terms of cost savings.

Consumers
If industry were to experience cost savings as a result of using this enzyme, industry may pass on some of the cost savings to consumers.

Government
Permitting the use of this enzyme as a processing aid may result in a small, inconsequential cost to government in terms of an addition to the current range of processing aids that are already monitored for compliance.

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 proposed use of beta-fructofuranosidase from GM *T. reesei* as a processing aid 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 schedule and standards apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

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 undertook a safety assessment (see SD1) and concluded there were no public health and safety concerns associated with the proposed use of this enzyme.

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

The labelling requirements for this enzyme are discussed in section 1.3.3 of this report.

2.5.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this application relevant to 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 used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of information and scientific literature as part of their application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application.

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

There are no Codex Alimentarius Standards for processing aids or enzymes. The enzyme processing aid would have to comply with international specifications for enzyme preparations, being the JECFA Combined Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes referred to in section 1.3.2.

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

The applicant has advised that it is seeking approval for the enzyme in Brazil, Canada, Denmark, the EU and the USA, as well as planning to submit to China, Thailand, Indonesia and South Korea. Approving the draft variation would bring Australia and New Zealand into line with other countries where use of the enzyme may be permitted in the future.

In this way, Australia and New Zealand would remain competitive with other international markets. This would also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment is there are no public health and safety concerns associated with the production microorganism or with using the enzyme as a food processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the proposed use of this alternative enzyme.

Ultimately, the domestic food industry will make their own economic decisions, taking into account the costs and benefits of using the new enzyme, to determine if it is of benefit to their particular business.

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

No issues were identified for this application relevant to this objective.

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

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[6] includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

[6] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that permitting the proposed use of this enzyme as a processing aid is consistent with these specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

3 References

FAO/WHO (2006) Combined compendium of food additive specifications, Food and Agriculture Organization of the United Nations, Rome. http://www.fao.org/docrep/009/a0691e/A0691E03.htm

FAO/WHO (2021). Compendium of Food Additive Specifications. Joint FAO/WHO Expert Committee on Food Additives (JECFA), 91st Meeting – Virtual meeting, 1–12 February 2021. FAO JECFA Monographs No. 26. Rome. https://doi.org/10.4060/cb4737en

IUBMB (2023) EC 3.2.1.26 https://iubmb.qmul.ac.uk/enzyme/EC3/2/1/26.html

The United States Pharmacopeia (2022) Food Chemicals Codex 13th Edition, United States Pharmacopeial Convention, Rockville, MD. http://publications.usp.org/

Attachments

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

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

Food Standards (Application A1278– Beta-Fructofuranosidase from GM *Trichoderma reesei* as a processing aid) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[insert Delegate's and position title]
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 A1278 – Beta-Fructofuranosidase from GM* Trichoderma reesei *as a processing aid) 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 18—Processing aids

[1] Subsection S18—9(3) (table)

Insert:

β-Fructofuranosidase (EC 3.2.1.26) sourced from *Trichoderma reesei* containing the β-fructofuranosidase gene from *Aspergillus niger*	For use in the production of short-chain fructooligosaccharides; and to produce a reduction in sugar levels in treated fruit and vegetable products	GMP

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1278 – Beta-Fructofuranosidase from GM* Trichoderma reesei *as a processing aid) 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 A1278 which sought to amend the Code to permit beta-fructofuranosidase (EC 3.2.1.26) from a genetically modified strain of *Trichoderma reesei* to be used as a processing aid in the production of short-chain fructooligosaccharides, and to produce a reduction in sugars levels in treated fruit and vegetable products. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1278 – Beta-Fructofuranosidase from GM* Trichoderma reesei *as a processing aid) 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 sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act

establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit beta-fructofuranosidase from genetically modified *Trichoderma reesei* to be used as a processing aid in the production of short-chain fructooligosaccharides, and to produce a reduction in sugar levels in treated fruit and vegetable products. This permission is subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with Good Manufacturing Practice (GMP).

4. Documents incorporated by reference

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

However, existing provisions of the Code incorporate documents by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 26 (2021)) and the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). These include general specifications for the identity and purity of enzyme preparations used in food processing.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1278 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 10 October 2023 for a six-week consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA). 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 processing aids and GM foods. This is because applications relating to permitting the use of processing aids and GM foods that have been determined to be safe are minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a RIS 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 A1278 – Beta-Fructofuranosidase from GM* Trichoderma reesei *as a processing aid) 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 commences on the date of gazettal of the instrument.

Item [1] of the Schedule to the variation amends Schedule 18 of the Code by inserting a new entry, in alphabetical order, into column 1 of the table to subsection S18—9(3). The new entry consists of the following enzyme:

- 'β-Fructofuranosidase (EC 3.2.1.26) sourced from *Trichoderma reesei* containing the β-fructofuranosidase gene from *Aspergillus niger*'

The International Union of Biochemistry and Molecular Biology uses the accepted name β-fructofuranosidase for the enzyme numbered EC 3.2.1.26 (IUBMB 2023). This is the name used in the variation and in Schedule 18 (subsection S18—4(5)). However, 'beta-fructofuranosidase' is referred to elsewhere in this Explanatory Statement to avoid using symbols in reports which can be hard to read on some platforms.

The permitted technological purpose for this enzyme is prescribed in column 2 of the table i.e. for use as a processing aid in the production of short-chain fructooligosaccharides; and to produce a reduction in sugar levels in treated fruit and vegetable products.

The permission is subject to the condition, as prescribed in column 3 of the table, that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP.

The effect of item [1] of the Schedule to the variation is to permit the proposed use of the enzyme β-fructofuranosidase (EC 3.2.1.26) sourced from *Trichoderma reesei* containing the β-fructofuranosidase gene from *Aspergillus niger* as a processing aid in accordance with the Code.

Attachment C – Draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1278– Beta-Fructofuranosidase from GM *Trichoderma reesei* as a processing aid) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[insert Delegate's and position title]
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 A1278 – Beta-Fructofuranosidase from GM* Trichoderma reesei *as a processing aid) 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 18—Processing aids

[1] Subsection S18—9(3) (table)

Insert:

β-Fructofuranosidase (EC 3.2.1.26) sourced from *Trichoderma reesei* containing the β-fructofuranosidase gene from *Aspergillus niger*	For use in the production of short-chain fructooligosaccharides; and to produce a reduction in sugar levels in treated fruit and vegetable products	GMP