

3 November 2023
268-23

Approval report – Application A1267

Fructanase 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 fructanase from genetically modified *Trichoderma reesei* to be used as a processing aid in the manufacture of bakery products.

On 6 July 2023, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received one submission.

FSANZ approved the draft variation on 25 October 2023. The Food Ministers' Meeting¹ was notified of FSANZ's decision on 3 November 2023.

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:

SD Risk and Technical Assessment

Executive summary

AB Enzymes GmbH applied 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 fructanase (EC 3.2.1.80)² as a processing aid in the manufacture of bakery products. The enzyme is a protein engineered variant of fructanase from *Lactobacillus crispatus*, produced by genetically modified (GM) *Trichoderma reesei*. The enzyme would be used at minimum levels necessary to achieve the desired effect, in accordance with Good Manufacturing Practice (GMP).

The proposed use of this fructanase enzyme as a processing aid in the manufacture of bakery products is consistent with its typical function of catalysing the hydrolysis of fructans.

Fructanase performs the above technological functions during the manufacture of bakery products and is not performing the technological purpose in the food for sale, therefore functioning as a processing aid for the purposes of the Code.

No public health and safety concerns were identified in the assessment of the fructanase produced by GM *T. reesei* for the proposed use. *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 microorganism is neither pathogenic nor toxigenic. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe for the proposed use. In the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) of 'not specified' is considered appropriate.

FSANZ called for submissions regarding a draft variation to the Code on 6 July 2023 for a five-week consultation period. FSANZ received one submission, which was from a government agency supporting the draft variation.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation amending the table to subsection S18—9(3) of the Code. The approved draft variation will permit the use of the protein engineered variant of the enzyme fructanase (EC 3.2.1.80) sourced from *T. reesei* containing the fructanase gene from *L. crispatus* as a processing aid in the manufacture of bakery products. The permission will be subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be an amount consistent with GMP. The effect of the approved draft variation will be to permit the proposed use of this enzyme as a processing aid in accordance with the Code.

² Fructanase is also known as fructan β -fructosidase (EC 3.2.1.80).

1 Introduction

1.1 The applicant

The applicant is AB Enzymes GmbH.

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 a protein engineered variant of the enzyme fructanase³ as a processing aid in the manufacture of bakery products. The enzyme is produced from genetically modified (GM) *Trichoderma reesei* containing the fructanase gene from *Lactobacillus crispatus*. Thus *T. reesei* is the host (source) species and *L. crispatus* is the donor for the fructanase gene.

The applicant's preparation containing this enzyme as the active constituent is a powdered product with the commercial name VERON FR.

The applicant indicated that the enzyme is to be used at minimum levels necessary to achieve the desired effect, in accordance with Good Manufacturing Practice (GMP).

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) 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 GMP.

Standard 1.3.3 and Schedule 18 of the Code list the 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

³ Fructanase is also known as fructan β -fructosidase (EC 3.2.1.80). Refer to Section 2.4.2 of this report for an explanation regarding naming of this enzyme.

- 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 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).

Fructanase is not currently permitted for use as a processing aid in the Code.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids in food 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 JECFA Monographs 26 (2021)), and the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). These include general specifications for enzyme preparations used in food processing for identity and purity parameters.

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.

Division 3 of Standard 1.2.3 requires declarations of certain foods (e.g. allergens) on the label of food for sale, unless an exemption applies. If the declaration relates to a processing aid, it must be made in the statement of ingredients and must include the required name⁴ for the food which is to be declared in conjunction with the words ‘processing aid’. If the requirement for a statement of ingredients does not apply, the required name must be declared on the label of the food for sale. If a food for retail sale is not required to bear a label, the required name must be displayed in connection with the display of the food or provided to the purchaser on request. If food sold to a caterer is not required to bear a label, the required name must be provided to the caterer with the food.

Section 1.5.2—4 of the Code requires a food for sale that consists of a *genetically modified food*⁵ (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

⁴ **Required name**, of a particular food, means the name declared by section 1.2.3—5 as the required name for that food for the purposes of Division 3 of Standard 1.2.3 (see subsection 1.1.2—2(3)).

⁵ 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*).

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, 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). In contrast to food additives, there is no Codex Alimentarius 'general standard' 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 *Food Standards Australia New Zealand Act 1991* (FSANZ Act), and
- 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 in the FSANZ Act.

1.7 Decision

For the reasons outlined in this report, FSANZ decided to approve a draft variation amending the Code to permit a protein engineered variant of the enzyme fructanase from genetically modified *Trichoderma reesei* to be used as a processing aid in the manufacture of bakery products.

The draft variation as proposed following assessment was approved with a typographical amendment. The approved draft variation takes effect on gazettal and 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.

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 6 July 2023 to 10 August 2023, with one submission received. The submitter, New Zealand Food Safety, supported the amendment to permit the use of a protein engineered variant of the enzyme fructanase from genetically modified *Trichoderma reesei* to be used as a processing aid in the manufacture of bakery products

2.2 Food technology assessment

From the food technology assessment, FSANZ concludes that the proposed use of the fructanase enzyme as a processing aid in the manufacture of bakery products is consistent with its typical function of catalysing the hydrolysis of fructans.

Fructanase performs its technological purpose during the production of food and is not performing the technological purpose in the food for sale. It is therefore functioning as a processing aid for the purposes of the Code.

2.3 Risk assessment

FSANZ has assessed the public health and safety risks associated with a protein engineered variant of the enzyme fructanase from GM *T. reesei* containing the fructanase gene from *L. crispatus* and its proposed use as a processing aid (see the SD). A summary of this risk assessment is provided below.

No public health and safety concerns were identified in the assessment of this fructanase enzyme produced by GM *T. reesei* for the proposed use.

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, and a biotechnology assessment confirmed the genetic modification is as described and that the inserted gene has been stably introduced.

A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use. Bioinformatics analysis confirmed that the produced enzyme itself has no significant similarity 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 (ADI) 'not specified' is appropriate.

Wheat flour is used as an ingredient in the applicant's enzyme preparation⁶.

2.4 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.

⁶ Enzymes are generally sold as enzyme preparations, which consist of the enzyme(s) and other ingredients.

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 proposed use of a protein engineered variant of the fructanase enzyme produced from GM *T. reesei* containing the fructanase gene from *L. crispatus* as a processing aid in the manufacture of bakery products and called for submissions on the draft variation.

Following the call for submissions and having regard to the submission received, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment with a typographical amendment (see Attachment A).

Risk management considerations for this application relating to the regulatory approval, the enzyme and source microorganism nomenclature, specifications and labelling are discussed below.

2.4.1 Regulatory approval for enzymes

As stated above, FSANZ has approved a draft variation to permit the use of the enzyme as a processing aid in the manufacture of bakery 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 1.3.1 of this report above). The enzyme is a food produced using gene technology for Code purposes as it is derived from 'an organism which has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code)⁷.

2.4.2 Nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name fructan β -fructosidase for the enzyme numbered EC 3.2.1.80. This is the name used in the approved draft variation. The synonym 'fructanase' has however, been used in this report and was used by the applicant in the application.

Nomenclature for the host and gene donor organisms – *Trichoderma reesei* and *Lactobacillus crispatus* respectively – is in accordance with accepted international norms for bacterial taxonomy.

There are relevant identity and purity specifications in primary sources of specifications listed in Schedule 3 for enzyme preparations used in food processing (refer to Section 1.3.2 above).

2.4.3 Labelling

Relevant labelling provisions in the Code will apply to foods for sale that are manufactured using this processing aid. See Section 1.3.3 above.

Section 2.2.1 of the SD states that wheat flour is used in the applicant's final enzyme preparation. When wheat and gluten (which may be present in wheat) are present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid, they must be declared in accordance with Division 3 of Standard 1.2.3 unless

⁷ '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'.

an exemption applies.

2.4.4 Risk management conclusion

The risk management conclusion is to permit a protein engineered variant of the enzyme fructanase (EC 3.2.1.80) produced from GM *T. reesei* containing the fructanase gene from *L. crispatus* for use as a processing aid in the manufacture of bakery 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 will have to be consistent with GMP. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code also provides the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

2.5 Risk communication

2.5.1 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.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

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

2.6 FSANZ Act assessment requirements

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

The Office of Impact Analysis⁸ granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting processing aids and GM foods is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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

⁸ Formerly known as the Office of Best Practice Regulation (OBPR).

status quo is rejecting the application). This analysis considered permitting the use of a protein engineered variant of the enzyme fructanase from GM *T. reesei* as a processing aid for use in the manufacture of bakery 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.

2.6.1.1.1 Costs and benefits of permitting the proposed use of this enzyme

Industry

Industry may benefit from a number of improvements and efficiencies from the use of this enzyme in the manufacture of bakery products. 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 proposed use of this enzyme 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.

2.6.1.1.2 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 this fructanase enzyme from GM *T. reesei* for use as a processing aid in the manufacture of bakery products, most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

2.6.1.2 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.

2.6.1.3 Any relevant New Zealand standards

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

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.6.2.1 Protection of public health and safety

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

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

The labelling requirements relevant to this application are discussed in Section 2.4.3 of this report.

2.6.2.3 The prevention of misleading or deceptive conduct

There were no issues identified with this application relevant to this objective.

2.6.3 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. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in the SD.

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

There are relevant international specifications for enzyme preparations as referred to in Section 1.3.2 of this report, with which this enzyme would have to comply.

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

The applicant is planning to seek permission to use their enzyme in a number of other countries: the European Union, Denmark, Canada, Mexico, and the United States of America. Approval of the draft variation would bring Australia and New Zealand into line with other jurisdictions if the enzyme is authorised for use in those countries. In this way, Australia and New Zealand will remain competitive with other international markets. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment is that there are no public health and safety concerns associated with the proposed use of 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 use of this enzyme for the various applications proposed by the applicant.

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*⁹ 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:

- 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 is consistent with these specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

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 (call for submissions)

⁹ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

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



Food Standards (Application A1267 – Fructanase from GM *Trichoderma reesei* as a processing aid) 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 this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name 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 A1267 – Fructanase 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:

Fructan β -fructosidase, protein engineered variant, (EC 3.2.1.80) sourced from <i>Trichoderma reesei</i> containing the fructan β -fructosidase gene from <i>Lactobacillus crispatus</i>	For use in the manufacture of bakery products	GMP
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[2] Subsection S18—9(3) (note after table)

Omit the dot point list of protein engineered variants of enzymes in the note, substitute:

- Endo-1,4- β -xylanase, protein engineered variant;
- Fructan β -fructosidase, protein engineered variant;
- Glucoamylase, protein engineered variant;
- Maltogenic α -amylase, protein engineered variant;
- Protein engineered enzymes used in the manufacture of various steviol glycosides.

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1267 – Fructanase 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 A1267 which sought to amend the Code to permit the use of a protein engineered variant of the fructanase enzyme (EC 3.2.1.80) from genetically modified *Trichoderma reesei* containing the fructanase gene from *Lactobacillus crispatus* to be used as a processing aid in the manufacture of bakery products. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards (Application A1267 – Fructanase 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 approved draft standard or 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 be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

The 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 S18—9(3) in Schedule 18 of the Code to permit the use of a protein engineered variant of the fructanase (EC 3.2.1.80) enzyme sourced from genetically modified *Trichoderma reesei* containing the fructanase gene from *Lactobacillus crispatus*, as a processing aid in the manufacture of bakery 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) Compendium of Food Additive Specifications (FAO JECFA Monographs 26 (2021)) and the United States Pharmacopeial Convention Food Chemicals Codex (13th edition, 2022). These include general specifications for the identity and purity parameters 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 A1267 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 6 July 2023 for a five-week consultation period.

The Office of Impact Analysis¹⁰ granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting processing aids and genetically modified foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting processing aids and genetically modified foods is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

¹⁰ Formerly known as the Office of Best Practice Regulation (OBPR)

7. Variation

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1267 – Fructanase 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 will commence on the date of gazettal of the instrument.

7.1 Item [1]

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

- 'Fructan β -fructosidase, protein engineered variant, (EC 3.2.1.80) sourced from *Trichoderma reesei* containing the fructan β -fructosidase gene from *Lactobacillus crispatus*'

The International Union of Biochemistry and Molecular Biology uses the accepted name 'fructan β -fructosidase' for the enzyme numbered EC 3.2.1.80, which is the name used in the variation. However, the synonym 'fructanase' was used by the applicant in the application and has been referred to in this Explanatory Statement.

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 manufacture of bakery 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 protein engineered variant of the enzyme fructanase (EC 3.2.1.80) sourced from a genetically modified *Trichoderma reesei* containing the fructanase gene from *Lactobacillus crispatus* as a processing aid in accordance with the Code.

7.2 Item [2]

Item [2] of the Schedule to the variation amends the Note after the table to subsection S18—9(3) by omitting the existing dot point list in the Note (the dot point list), and substituting it with a new dot point list. The dot point list is a list of protein engineered variants of enzymes that are listed in the table to subsection S18—9(3) as permitted processing aids for specific technological purposes; and the new list includes 'Fructan β -fructosidase, protein engineered variant;', which is inserted in the table by item [1] of the variation (see above).

The existing protein engineered variants of enzymes are relisted in alphabetical order in the new dot point list.

The Note after the table to subsection S18—9(3) relates to protein engineered variants of enzymes, which are listed in the table to subsection S18—9(3) as processing aids permitted to be used for specific technological purposes. The Note explains that if such an enzyme is used as a processing aid, the resulting food may have as an ingredient a food produced using gene technology, and the requirements relating to foods produced using gene

technology in the Code will apply (see Standard 1.2.1 and Standard 1.5.2). The Note then lists the relevant substances.

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



Food Standards (Application A1267 – Fructanase from GM *Trichoderma reesei* as a processing aid) 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 this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name 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 A1267 – Fructanase 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:

Fructan β -fructosidase, protein engineered variant, (EC 3.2.1.80) sourced from <i>Trichoderma reesei</i> containing the fructan β -fructosidase gene from <i>Lactobacillus crispatus</i>	For use in the manufacture of bakery products	GMP
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[2] Subsection S18—9(3) (note after table)

Omit the dot point list of protein-engineered variants of enzymes in the note, substitute:

- Endo-1,4- β -xylanase, protein engineered variant;
- Fructan β -fructosidase, protein engineered variant;
- Glucoamylase, protein engineered variant;
- Maltogenic α -amylase, protein engineered variant;
- Protein engineered enzymes used in the manufacture of various steviol glycosides.