

**6 July 2023**  
**250-23**

## **Call for submissions – Application A1267**

### **Fructanase from GM *Trichoderma reesei* as a processing aid**

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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 and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made by emailing your submission to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au). FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 10 August 2023**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making a submission or application and proposal processes can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Submissions in hard copy may be sent to the following addresses:

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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 has 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)<sup>1</sup> 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 has therefore prepared a draft variation to subsection S18—9(3) of the Code. The draft variation, if approved, would 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 would 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.

FSANZ seeks submissions on the draft variation.

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<sup>1</sup> Fructanase is also known as fructan  $\beta$ -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 is to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of a protein engineered variant of the enzyme fructanase<sup>2</sup> 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 has 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 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
- if no food is specified—any food.

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<sup>2</sup> Fructanase is also known as fructan  $\beta$ -fructosidase (EC 3.2.1.80). Refer to Section 2.3.2 of this report for an explanation regarding naming of this enzyme.

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 23 (2019)), and the United States Pharmacopeial Convention (2020) Food chemicals codex (12<sup>th</sup> 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 name<sup>3</sup> 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 requires a food for sale that consists of a *genetically modified food*<sup>4</sup> (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.

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<sup>3</sup> **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)).

<sup>4</sup> Section 1.5.2—4(5) defines **genetically modified food** to mean a '\*food produced using gene technology that

- contains novel DNA or novel protein; or
- 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 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 is being assessed under the General Procedure in the FSANZ Act.

# 2 Summary of the assessment

## 2.1 Food technology assessment

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.

## 2.2 Risk assessment

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

No public health and safety concerns were identified in the assessment of 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 organism is neither pathogenic nor toxigenic.

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 preparation<sup>5</sup>.

## 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.

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code permitting the use of fructanase enzyme produced from GM *T. reesei* containing the fructanase gene from *L. crispatus* as a processing aid in the manufacture of bakery products. If approved, 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.

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.

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

### 2.3.1 Regulatory approval for enzymes

As stated above, FSANZ has prepared 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)<sup>6</sup>.

### 2.3.2 Nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name fructan  $\beta$ -fructosidase for the enzyme numbered EC 3.2.1.80. This is the name used in the proposed 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).

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<sup>5</sup> Enzymes are generally sold as enzyme preparations, which consist of the enzyme(s) and other ingredients.

<sup>6</sup> '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'.

### **2.3.3 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 an exemption applies.

### **2.2.4 Risk management conclusion**

The risk management conclusion is to permit the enzyme fuctanase (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. If approved, the permission would 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 must 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 also provides the 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.

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

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received from this call for submissions.

### **2.4.2 World Trade Organization (WTO)**

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

There are no relevant international standards (i.e., Codex Alimentarius Standards) and amending the Code to approve the enzyme as a processing aid is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## **2.5 FSANZ Act assessment requirements**

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:



## 2.5.1 Section 29

### 2.5.1.1 Consideration of costs and benefits

The Office of Impact Analysis<sup>7</sup> 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, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where status quo is rejecting the application). This analysis considers permitting the use 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 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 use of this processing aid.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from the Call for Submissions may result in FSANZ arriving at a different outcome.

#### 2.5.1.1.1 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.

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<sup>7</sup> Formerly known as the Office of Best Practice Regulation (OBPR).

#### *2.5.1.1.2 Conclusions from cost benefit considerations*

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting fructanase from GM *T. reesei* for use as a processing aid in the manufacture of bakery products, most likely outweigh the associated costs.

#### **2.5.1.2 Other measures**

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than 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 other 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 the SD) 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 relevant to this application are discussed in Section 2.3.3 of this report.

#### **2.5.2.3 The prevention of misleading or deceptive conduct**

There were 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. 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. If the draft variation is approved, it would bring Australia and New Zealand into line with other jurisdictions once authorised for use in those countries. 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 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*<sup>8</sup> 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.

### **3 Draft variation**

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft 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.

## **Attachments**

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<sup>8</sup> <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

- A. Draft variation to the Australia New Zealand Food Standards Code
- B. Draft Explanatory Statement

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



### Food Standards (Application A1267 – Fructanase 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 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 $\beta$ -fructosidase, protein engineered variant, (EC 3.2.1.80) sourced from <i>Trichoderma reesei</i> containing the fructan $\beta$ -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- $\beta$ -xylanase, protein engineered variant;
- Fructan  $\beta$ -fructosidase, protein engineered variant;
- Glucoamylase, protein engineered variant;
- Maltogenic  $\alpha$ -amylase, protein engineered variant;
- Protein engineered enzymes used in the manufacture of various steviol glycosides.

# Attachment B – Draft 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 seeks 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 prepared a draft variation – the *Food Standards (Application A1267 – Fructanase from GM *Trichoderma reesei* as a processing aid) Variation*.

#### **2. Variation will be a legislative instrument**

If approved, the draft variation would be 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](http://www.legislation.gov.au)).

If approved, this instrument would not be 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 Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

### **3. Purpose**

The Authority has prepared 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. If approved, this permission would be 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 draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that would prescribe identity and purity specifications for the processing aid to be permitted by the 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/WHO 2019) and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition). 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will occur for a six-week consultation period.

The Office of Impact Analysis<sup>9</sup> 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**

If approved, this instrument would be 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*.

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<sup>9</sup> Formerly known as the Office of Best Practice Regulation (OBPR)



## 7. Variation

### 7.1 Item [1]

**Item [1]** of the Schedule to the draft variation would insert 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  $\beta$ -fructosidase, protein engineered variant, (EC 3.2.1.80) sourced from *Trichoderma reesei* containing the fructan  $\beta$ -fructosidase gene from *Lactobacillus crispatus*'

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

The permitted technological purpose for this enzyme would be prescribed in column 2 of the table i.e. for use as a processing aid in the manufacture of bakery products.

The permission would be 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.

If approved, **item [1]** of the draft variation would 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 draft variation would amend 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 would include 'Fructan  $\beta$ -fructosidase, protein engineered variant;', which would be inserted in the table by item [1] of the draft variation (see above).

The existing protein-engineered variants of enzymes would be 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.