

19 June 2023

247-23

Approval report – Application A1228

Endo-1,4-beta-xylanase from GM *Trichoderma reesei* (gene donor: *Talaromyces leycettanus*) as a processing aid

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Australia Pty Ltd to permit the use of endo-1,4-beta-xylanase (EC 3.2.1.8) from a genetically modified strain of *Trichoderma reesei* as a processing aid for use in brewing, fats and oils processing, grain processing and potable alcohol production.

On 8 February 2023, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 7 June 2023. The Food Ministers' Meeting¹ was notified of FSANZ's decision on 19 June 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:

SD1 Risk and technical assessment

Executive summary

Novozymes Australia Pty Limited applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of endo-1,4-beta-xylanase (EC 3.2.1.8) from a genetically modified (GM) strain of *Trichoderma reesei* (*T. reesei*) as a processing aid for use in brewing, fats and oils processing, grain processing and potable alcohol production.

The enzyme is sourced from a genetically modified (GM) strain of *T. reesei* containing the endo-1,4-beta-xylanase gene from *Talaromyces leycettanus* (*T. leycettanus*).

FSANZ concludes that the proposed use of the enzyme in brewing, fats and oils processing, grain processing and potable alcohol production is technologically justified for use at levels consistent with Good Manufacturing Process (GMP). Analysis of the evidence provides adequate assurance that the use of this enzyme, in the quantity and form proposed, is justified.

FSANZ completed a risk assessment and concluded there are no public health and safety concerns associated with the proposed use of this enzyme. In the absence of any identifiable hazard, an acceptable daily intake (ADI) '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 8 February 2023 to 22 March 2023. FSANZ received two submissions, both supportive of the draft variation.

Based on the information above and for the reasons set out in this report, FSANZ has approved a draft variation to the table to subsection S18—9(3) of the Code to permit the use of the enzyme endo-1,4-beta-xylanase (EC 3.2.1.8) sourced from *T. reesei* containing the endo-1,4-beta-xylanase gene from *T. leycettanus* as a processing aid. The enzyme will be permitted for use in brewing, fats and oils processing, grain processing and potable alcohol production.

This permission is subject to the condition that the maximum permitted level of the enzyme that may be present in the food is 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.

1 Introduction

1.1 The applicant

Novozymes Australia Pty Ltd is a manufacturer of enzymes, microorganisms and precision proteins.

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 endo-1,4-beta-xylanase (EC 3.2.1.8) from a genetically modified (GM) strain of *Trichoderma reesei* (*T. reesei*) as a processing aid. The enzyme is sourced from a GM strain of *T. reesei* containing the endo-1,4-beta-xylanase gene from *Talaromyces leycettanus* (*T. leycettanus*).

The intended purpose for use of the enzyme is in brewing, fats and oils processing, grain processing and potable alcohol production.

The applicant markets the enzyme as a liquid preparation containing the active constituent with the commercial name Novozym 28255.

The applicant has indicated the enzyme is to be used at minimum levels necessary to achieve the technological purpose, 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 relevant requirements for 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 processing that meets all the following conditions:

- it is used to perform a technological purpose during 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
- 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).

Endo-1,4-beta-xylanase from *T. reesei* is already permitted to be used as a processing aid by the Code, but not from *T. reesei* containing for gene for endo-1,4-beta-xylanase from *T. leycettanus* as requested by the applicant.

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 JECFA Monographs 23, 2019), and the United States Pharmacopeial Convention (USPC 2020) Food chemicals codex (12th edition). These 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 label 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). 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

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*).

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)
- 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 reasons outlined in this report, FSANZ decided to approve a draft variation amending the Code to permit the use of this enzyme as a processing aid in brewing, fats and oils processing, grain processing and potable alcohol production.

The draft variation as proposed following assessment was approved without change. 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.

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 8 February 2023 to 22 March 2023. Two submissions were received. Both submitters supported permitting the use of the new GM microbial source for the enzyme endo-1,4-beta-xylanase as a processing aid in brewing, fats and oils processing, grain processing and potable alcohol production.

The submissions were received from:

- New Zealand Food Safety
- New Zealand Food and Grocery Council.

2.2 Risk assessment

FSANZ has assessed the public health and safety risks associated with endo-1,4-beta-xylanase from *T. leycettanus* that is produced by GM *T. reesei* and its proposed use as a processing aid. A summary of this risk assessment is provided below.

The proposed use of this endo-1,4-beta-xylanase as a processing aid for brewing, fats and oils processing, grain processing and potable alcohol production is technologically justified.

No public health and safety concerns were identified in the assessment of endo-1,4-beta-xylanase from GM *T. reesei* under the proposed conditions of use. A microbiological assessment concluded that *T. reesei* has a long history of safe use in food and is neither pathogenic nor toxigenic. A biotechnology assessment confirmed the presence and stability of the inserted DNA. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under proposed conditions of use.

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 to 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 at levels consistent with GMP.

FSANZ therefore considered it appropriate to prepare a draft variation amending the Code to permit the proposed use of this enzyme and called for submissions on the draft variation.

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

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

2.3.1 Regulatory approval for enzymes

Endo-1,4-beta-xylanase performs its technological purpose during brewing, fats and oils processing, grain processing and potable alcohol production. The enzyme does not perform a technological purpose in the final food. On that basis, the enzyme functions as a processing aid for the purposes of the Code. Based on the food technology assessment, FSANZ concluded that the proposed use of this enzyme is consistent with its typical function of hydrolysing xylosidic linkages in xylans, including arabinoxylan present in grains, for further processing.

The express permission for the enzyme to be used as a processing aid will also provide the permission for its potential presence in the food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology according to the Code as it is derived from 'an organism that has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code)³.

2.3.2 Nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name 'endo-1,4 β-xylanase'. This is the name used in some existing permissions in Schedule 18. The name endo-1,4-beta-xylanase is used in this report including for the approved draft variation and is consistent with existing permissions in subsection S18—4(5).

Nomenclature for the host and gene donor organisms (*Trichoderma reesei* and *Talaromyces leycettanus* respectively) is in accordance with accepted international norms (see Section 1.2 of this report).

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'.

There are relevant identity and purity specifications for the enzyme in two of the primary sources of specifications listed in Schedule 3, namely the JECFA Combined Compendium of Food Additive Specifications and the United States Pharmacopeial Convention Food chemicals codex (see Section 1.3.2).

2.3.3 Labelling

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 is to permit the enzyme endo-1,4-beta-xylanase (EC 3.2.1.8) sourced from a GM strain of *T. reesei* containing the endo-1,4-beta-xylanase gene from *T. leycettanus* for use as a food processing aid. The permission will be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The technological purpose of this enzyme will be for use as a processing aid in brewing, fats and oils processing, grain processing and potable alcohol production. The maximum level at which the enzyme may be present in the food will 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 would also provide 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 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 all 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

The Office of Impact Analysis (OIA)⁴ granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to processing aids and genetically modified foods (OIA correspondence dated 24 November 2010,

⁴ Formerly known as the Office of Best Practice Regulation (OBPR).

reference 12065). This standing exemption was provided as permitting new GM foods and new processing aids 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. This analysis considers permitting the use of the enzyme endo-1,4-beta-xylanase, sourced from the GM strain of *T. reesei* for use in brewing, fats and oils processing, grains processing, and potable alcohol production.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measure. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting the proposed use of the enzyme endo-1,4-beta-xylanase enzyme sourced from the GM strain of *T. reesei*.

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

Costs and benefits of permitting the use of endo-1,4-beta-xylanase enzyme sourced from the GM strain of T. reesei as a processing aid

Industry

Due to the voluntary nature of the permission, industry will only use the enzyme where they believe a net benefit exists for them. Industry may benefit from having additional choice available to them for brewing, fats and oils and grains processing, and potable alcohol production.

The enzyme is approved in other countries including Brazil, Denmark, and Mexico, which may be an opportunity for Australia and New Zealand industries, although there may be competing imports from these countries into the domestic market.

Consumers

Consumers may benefit from a greater availability of foods. Industry may pass on some of any cost reductions onto consumers through lower prices.

Government

Permitting the proposed use of this endo-1,4-beta-xylanase enzyme may result in a small and inconsequential cost to government in terms of adding it to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the proposed use of the enzyme endo-1,4-beta-xylanase from GM *T. reesei* (as a processing aid in brewing, fats and oils processing, grains processing, and potable alcohol production) most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.5.1.3 Any relevant New Zealand standards

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

2.5.1.4 Any other relevant matters

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 2.3.3 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. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other relevant technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in SD1.

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

There are relevant international specifications for enzyme preparations, being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes referred to in Section 1.3 of this report, with which this enzyme must comply.

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

The applicant advised that their endo-1,4-beta-xylanase preparation is used in a range of countries, where there are no restrictions on the use of enzyme processing aids or where the enzyme is covered by a country positive list or specific approval. They also advised that their enzyme preparation has been approved for use in Brazil, Denmark and Mexico.

Approval for use brings Australia and New Zealand into line with other countries where it is already permitted for use. 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 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 this alternative enzyme for use at levels and for the purpose proposed by the applicant.

Ultimately, food businesses will make their own economic decisions, taking into consideration the costs and benefits of using the new enzyme, to determine if it is of benefit to their 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*⁵ 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

⁵ [Food regulation website](#)

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



Food Standards (Application A1228 – Endo-1,4-beta-xylanase from GM *Trichoderma reesei* (gene donor: *Talaromyces leycettanus*) 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 Delegate*]

[*Name and position of Delegate*]

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 A1228 – Endo-1,4-beta-xylanase from GM Trichoderma reesei (gene donor: Talaromyces leycettanus) 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:

Endo-1,4-beta-xylanase (EC 3.2.1.8) sourced from *Trichoderma reesei* containing the endo-1,4-beta-xylanase gene from *Talaromyces leycettanus*

For use in:

- (a) brewing; and
- (b) fats and oils processing; and
- (c) grain processing; and
- (d) the production of potable alcohol.

GMP

Attachment B

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1228 – Endo-1,4-beta-xylanase from GM *Trichoderma reesei* (gene donor: *Talaromyces leycettanus*) 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 purpose of the application was to permit the use of the enzyme endo-1,4-beta-xylanase (EC 3.2.1.8) sourced from a GM strain of *Trichoderma reesei* containing the endo-1,4-beta-xylanase gene from *Talaromyces leycettanus*, as a processing aid in brewing, fats and oils processing, grain processing and potable alcohol production. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards (Application A1228 – Endo-1,4-beta-xylanase from GM *Trichoderma reesei* (gene donor: *Talaromyces leycettanus*) 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 will be a legislative instrument

The approved draft variation, is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then

administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme endo-1,4-beta-xylanase (EC 3.2.1.8) sourced from a GM strain of *Trichoderma reesei* containing the endo-1,4-beta-xylanase gene from *Talaromyces leycettanus*, as a processing aid in brewing, fats and oils processing, grain processing and potable alcohol production. This permission is subject to the condition that the amount of enzyme used 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 23 (2019)) and the United States Pharmacopeial Convention Food Chemicals Codex (12th edition, 2020). 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 A1228 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 8 February 2023 for a six-week consultation period.

The Office of Impact Analysis⁶ granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting new processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids and GM foods is deregulatory as their use will be voluntary if the application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

6. Statement of compatibility with human rights

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

7. Variation

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

- 'Endo-1,4-beta-xylanase (EC 3.2.1.8) sourced from *Trichoderma reesei* containing the endo-1,4-beta-xylanase gene from *Talaromyces leycettanus*.'

⁶ Formerly known as the Office of Best Practice Regulation (OBPR).

The permitted technological purpose for this enzyme is prescribed in column 2 of the table for use in brewing, fats and oils processing, grain processing and potable alcohol production.

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 the approved draft variation is to permit the proposed use of endo-1,4-beta-xylanase (EC 3.2.1.8) sourced from *Trichoderma reesei* containing the endo-1,4-beta-xylanase gene from *Talaromyces leycettanus* as a processing aid in accordance with the Code.