11 May 2026
394-26

Approval report – Application A1304

Endo-1,4-beta-xylanase from *Bacillus licheniformis* (gene donor: *Chryseobacterium cucumeris*) for use as a processing aid

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novonesis to amend the Australia New Zealand Food Standards Code to permit the use of the enzyme endo-1,4-beta-xylanase (EC 3.2.1.8) as a processing aid in the production of potable alcohol and starch and gluten fractions.

On 11 December 2025, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 29 April 2026. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 11 May 2026.

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

Table of contents

Supporting document

The following document, which informed the assessment of this application, is available on the A1304 page on the FSANZ website:

SD Risk and Technical Assessment

The published submissions from the call for submissions can be found on the A1304 Consultation Hub page.

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from Novonesis to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme endo-1,4-beta-xylanase (E.C. 3.2.1.8) from *Bacillus licheniformis* containing the endo-1,4-beta-xylanase gene from *Chryseobacterium cucumeris* as a processing aid in the production of distilled alcohol[2] and production of starch and gluten fractions.

FSANZ's assessment concluded that the proposed use of endo-1,4-beta-xylanase is technologically justified in the quantity and form stated by the applicant to hydrolyse xylosidic linkages in xylans present in grains for production of potable alcohol and starch and gluten fractions. The enzyme does not perform a technological function in the food for sale, therefore functioning as a processing aid for purposes of the Code. There are relevant identity and purity specifications for the enzyme in the Code with which the enzyme must comply when added to food in accordance with the Code or sold for such use.

FSANZ concluded there are no public health or safety concerns associated with the use of endo-1,4-beta-xylanase produced from the *B. licheniformis* strain under the proposed conditions of use.

Following assessment, FSANZ prepared a draft variation to the Code and called for submissions on that draft variation on 11 December 2025, with a 7-week consultation period. FSANZ received 2 submissions. One submission supported approval of the draft variation. The other did not support approval of the draft variation, based on concerns regarding genetically modified foods.

Following consideration of these submissions and for the reasons outlined in this report, FSANZ has approved the draft variation proposed at the call for submissions with typographical and formatting amendments.

The approved draft variation will amend the table to subsection S18—9(3) of the Code to list the enzyme endo-1,4-beta-xylanase (E.C. 3.2.1.8) from *Bacillus licheniformis* containing the xylanase gene from *Chryseobacterium cucumeris* and its technological purpose. The table to subsection S18—9(3) lists substances (including enzymes) permitted to be used as processing aids for specific technological purposes. The technological purpose of this enzyme will be for use in the production of potable alcohol and the production of starch and gluten fractions. The permission will be subject to the condition that the enzyme must be used in accordance with Good Manufacturing Practice.

The effect of the approved draft variation will be to permit the use of endo-1,4-beta-xylanase (E.C. 3.2.1.8) from *B. licheniformis* containing the xylanase gene from *Chryseobacterium cucumeris* as a processing aid in accordance with the Code.

[2] The term 'potable alcohol' is used in this report and in the approved draft variation. See section 1.2 for further information.

1 Introduction

1.1 The applicant

The applicant is Novonesis. At the time the application was submitted to Food Standards Australia New Zealand (FSANZ), the applicant was Novozymes Australia Ptd Ltd. This change reflects a subsequent merger between Novozymes and Chr. Hansen, resulting in the formation of Novonesis. Novonesis is referred to as the applicant throughout this report.

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 the enzyme endo-1,4-beta-xylanase (EC 3.2.1.8) from *Bacillus licheniformis* containing the endo-1,4-beta-xylanase gene (xylanase gene) from *Chryseobacterium cucumeris* as a processing aid in the production of distilled alcohol and starch and gluten fractions.

Although the application refers to 'distilled alcohol', the term 'potable alcohol' has been used in this report and in the approved draft variation. The permissions already in subsection S18—9(3) for similar enzymes refer to 'potable alcohol' rather than distilled alcohol, which reflects that the terms are used interchangeably in the beverage industry. The applicant confirmed that 'potable alcohol' is appropriate in this case.

The enzyme is referred to in this report as endo-1,4-beta-xylanase.

The applicant has indicated the enzyme would be used in accordance with the principles of Good Manufacturing Practice (GMP)[3].

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 the use of that substance 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 of the following conditions:

[3] GMP is defined in the Standard 1.1.2—2 of the Code as follows: ***GMP*** or ***Good Manufacturing Practice***, *with respect to the addition of substances used as food additives and substances used as processing aids to food, means the practice of:*
(a) limiting the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect; and
(b) to the extent reasonably possible, reducing the amount of the substance or its derivatives that:
*(i) remains as a *component of the food as a result of its use in the manufacture, processing or packaging; and*
(ii) is not intended to accomplish any physical or other technical effect in the food itself
(c) preparing and handling the substance in the same way as a food ingredient.

- 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. An enzyme of microbial origin listed in the table to subsection S18—4(5) is 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.

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.

Endo-1,4-beta-xylanase from *B. licheniformis* containing the endo-1,4-beta-xylanase gene from *C. cucumeris* is not listed in the table to subsection S18—9(3) and therefore is not currently a permitted processing aid for use in food processing.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) requires substances used as processing aids in food to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code or sold for use in food.

Subsection S3—2(1) 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.

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 ‘general standard’ for processing aids. However, as noted in section 1.3.2 above, there are internationally recognised specifications

for enzyme preparations established by JECFA and Food Chemicals Codex.

Additionally, 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.

1.4.1 Overseas regulations

Endo-1,4-beta-xylanase from *B. licheniformis* has been evaluated as safe under the intended conditions of use by the European Food Safety Authority (EFSA) and has been approved for use in Denmark, Mexico, Brazil and France. The United States Food and Drug Administration (US FDA) provided a 'no questions' response to Novozyme's GRAS notification (GRN No. 728).

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 accordance with the FSANZ Act.

1.7 Decision

Following assessment, FSANZ prepared a draft variation proposing to amend the Code to permit the use of the enzyme endo-1,4-beta-xylanase (E.C. 3.2.1.8) from *B. licheniformis* containing the xylanase gene from *Chryseobacterium cucumeris* as a processing aid in the production of potable alcohol and starch and gluten fractions.

For the reasons outlined in this report and after consideration of submissions received during the consultation period, FSANZ approved the draft variation proposed at the call for submissions with typographical and formatting amendments. 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 received 2 submissions to the CFS, which are publicly available on the A1304 Consultation Hub page.

New Zealand Food Safety supported approval of the draft variation. An individual submitter did not support approval of the draft variation. FSANZ's response to that submission is provided in Table 1 below.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
Not supportive of FSANZ's assessment and the draft regulatory measure. The changes remove the right of the consumer to decide whether to consume GMO based foods.	Individual	FSANZ notes the submission. The enzyme is not considered a GM food for Code purposes and has been assessed as safe.

2.2 Food technology assessment

FSANZ completed a food technology assessment to determine whether the enzyme achieves its technological purpose in the quantity and form proposed in the application (see SD).

The food technology assessment concluded endo-1,4-beta-xylanase performs its technological purpose during the production of potable alcohol and production of starch and gluten fractions. It is inactivated by temperature during production and is not performing a technological purpose in the food for sale. It is therefore functioning as a processing aid for the purposes of the Code.

2.3 Risk assessment

FSANZ did not identify any public health and safety concerns associated with the use of endo-1,4-beta-xylanase from *B. licheniformis* containing the xylanase gene from *C. cucumeris* under the proposed use conditions. The production organism is neither pathogenic nor toxigenic. Analysis of the production strain confirmed the presence and stability of the inserted DNA.

Endo-1,4-beta-xylanase was not genotoxic *in vitro* or *in vivo*, and no homology was found with any known toxins or food allergens. The No Observed Adverse Effect Level (NOAEL) in a 13-week oral toxicity study in rats was 962 mg total organic solids (TOS)/kg bw/day.

The theoretical maximum daily intake (TMDI) of the TOS from the enzyme preparation was calculated to be 0.47 mg TOS/kg bw/day. A comparison of the NOAEL and the TMDI results in a margin of exposure (MOE) of approximately 2,000.

Based on the reviewed data it is concluded that an acceptable daily intake (ADI) 'not specified' is appropriate.

2.4 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation during a period of seven weeks.

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

- approve the draft variation proposed at the call for submissions, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or

- reject that draft variation.

FSANZ's risk and technical assessment concluded the proposed use of endo-1,4-beta-xylanase as a processing aid is technologically justified and that there are no safety concerns associated with the use of the enzyme.

Having regard to the submissions received and, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed at the call for submissions with typographical and formatting amendments (Attachment A).

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

2.4.1 Regulatory approval for processing aids

As stated above, FSANZ has approved a draft variation to permit the use of this enzyme as a processing aid in the production of potable alcohol and production of starch and gluten fractions.

2.4.2 Enzyme nomenclature, source microorganism nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB) lists the accepted name 'endo-1,4-beta-xylanase' for the enzyme EC 3.2.1.8 (see section 2.1 of SD). This is the name used in the approved draft variation.

Nomenclature for the production organism is *B. licheniformis* is in accordance with accepted international norms for 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 of this report). This enzyme would have to comply with those specifications when added to food in accordance with the Code or sold for use in food.

2.4.3 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 of this report).

2.4.4 Risk management conclusion

The risk management conclusion is to permit the enzyme endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *B. licheniformis containing the endo-1,4-beta-xylanase gene from Chryseobacterium cucumeris* as a processing aid for the production of potable alcohol and production of starch and gluten fractions.

The enzyme and its associated technological purpose 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 must be an amount consistent with GMP.

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 who made 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 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

FSANZ had 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 (as per paragraph 29(2)(a) of the FSANZ Act).

FSANZ assessed that a Regulation Impact Statement was not required for this application. This is because applications relating to permitting processing aids are determined to be safe, and considered minor in impact or deregulatory in nature, if their use will be voluntary if the draft variation concerned is approved.

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 seeks to highlight the potential positives and negatives of moving away from the status quo by permitting the proposed use of this enzyme endo-1,4-beta-xylanase (E.C. 3.2.1.8) as a processing aid in the production of potable alcohol and starch and gluten fractions.

Consumers
FSANZ's risk assessment concluded there are no safety concerns from permitting the applicant's processing aid. Consumers in Australia and New Zealand may benefit from marginal price reductions of food products that are produced using this enzyme as a processing aid. That is assuming permitting the proposed use of the enzyme as a processing aid through increased efficiency, reduces costs of producing those food products, and manufacturers pass-on a portion of any cost reductions to consumers.

Industry
Industry may benefit from increased choice of processing aids to produce alcoholic drinks and other food products. That may increase production efficiency and marginally reduce production costs. Industry may voluntarily use this enzyme as a processing aid where they

believe a commercial net benefit exists for them.

Government
The approval of this application may result in a small but likely inconsequential cost to government in terms of an addition to the current range of processing aids monitored for compliance.

Conclusion
FSANZ's assessment at the call for submissions stage was that the direct and indirect benefits that would arise from permitting the proposed use of the enzyme endo-1,4-beta-xylanase (E.C. 3.2.1.8) as a processing aid as proposed are likely to 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 standards in the Code that are relevant to the permitted use of processing aids 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 and concluded there were no public health and safety concerns associated with the proposed use of this enzyme (see section 2.3 of this report and the SD).

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 processing aid are discussed in sections 1.3.3 and 2.4.3 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, which is provided in the SD - Risk and Technical Assessment. The applicant submitted a dossier of information and scientific literature as part of their application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application.

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

In terms of food safety, the relevant international standard setting body is Codex. There is no Codex 'general standard' for processing aids, however as noted in section 1.3.2 of this report, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex, with which this enzyme would have to comply when added to food in accordance with the Code or sold for use in food.

There is also 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 (see section 1.4 of this report).

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

Australia and New Zealand will remain competitive with international markets where approval for the use of the enzyme is granted. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk and technical assessment is that there are no public health and safety concerns associated with the proposed use of this enzyme as a processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the uses of this enzyme proposed by the applicant. Ultimately, the 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 consideration.

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

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals* 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)

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

Food Standards (Application A1304 – Endo-1,4-beta-xylanase from *Bacillus licheniformis* (gene donor: *Chryseobacterium cucumeris*) for use 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 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 A1304 – Endo-1,4-beta-xylanase from* Bacillus licheniformis *(gene donor:* Chryseobacterium cucumeris*) for use 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 *Bacillus licheniformis* containing the endo-1,4-beta-xylanase gene from *Chryseobacterium cucumeris*	For use in the production of: (a) potable alcohol; and (b) starch and gluten fractions.	GMP

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1304 – Endo-1,4-beta-xylanase from* Bacillus licheniformis *(gene donor:* Chryseobacterium cucumeris*) for use 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 A1304 which sought to permit the use of the enzyme endo-1,4-beta-xylanase (E.C. 3.2.1.8) from *Bacillus licheniformis* containing the xylanase gene from *Chryseobacterium cucumeris* as a processing aid in the production of potable alcohol and the production of starch and gluten fractions. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1304 – Endo-1,4-beta-xylanase from* Bacillus licheniformis *(gene donor:* Chryseobacterium cucumeris*) for use as a processing aid) Variation* (the approved draft 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 variation.

2. Variation is a legislative instrument

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

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

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

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

3. Purpose

The Authority has approved a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme endo-1,4-beta-xylanase (E.C. 3.2.1.8) sourced from *Bacillus licheniformis* containing the endo-1,4-beta-xylanase gene from *Chryseobacterium cucumeris* as a processing aid in the production of potable alcohol and production of starch and gluten fractions. 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 would 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 when added to food in accordance with the Code or sold for use in food. 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 2021) and the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th 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 A1304 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. FSANZ called for submissions on the draft variation on 11 December 2025 for a 7-week consultation period.

A regulation impact statement (RIS) was not prepared because FSANZ's assessment was that a RIS was not required for this application. This was on the basis that the application was minor and deregulatory in nature. It sought to permit the use of a processing aid found to be safe and that use is voluntary. This position is consistent with previous advice from the Office of Impact Analysis (OIA) (OIA23-06225) when the OIA undertook assessments of whether a RIS was required for these types of applications.

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

References to ‘variation’ in this section are references to the approved draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1304 – Endo-1,4-beta-xylanase from* Bacillus licheniformis *(gene donor:* Chryseobacterium cucumeris*) for use as a processing aid) Variation.*

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation commences on the date of gazettal of the instrument.

Schedule to the variation

Item [1] of the Schedule to the 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 (E.C. 3.2.1.8) sourced from *Bacillus licheniformis* containing the endo-1,4-beta-xylanase gene from *Chryseobacterium cucumeris*’

The permitted technological purpose for this enzyme is prescribed in column 2 of the table i.e. for use in the production of potable alcohol and the production of starch and gluten fractions.

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 amendment in item [1] is to permit the proposed use of the enzyme, endo-1,4-beta-xylanase (E.C. 3.2.1.8) sourced from *Bacillus licheniformis* containing the endo-1,4-beta-xylanase gene from *Chryseobacterium cucumeris* as a processing aid in accordance with the Code.

Attachment C – Draft variation to the Australia New Zealand Food Standards Code (Call for Submissions)

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Food Standards (Application A1304 – Endo-1,4-beta-xylanase from *Bacillus licheniformis* (gene donor: *Chryseobacterium cucumeris*) for use 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 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 A1304 – Endo-1,4-beta-xylanase from* Bacillus licheniformis *(gene donor:* Chryseobacterium cucumeris*) for use 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 *Bacillus licheniformis* containing the endo-1,4-beta-xylanase gene from *Chryseobacterium cucumeris*	For use in the production of: (a) potable alcohol; and (b) starch and gluten fractions.	GMP