**11 May 2026**
**394-26**

# Approval report – Application A1305

# Alpha-amylase from *Bacillus licheniformis* (containing the gene for alpha-amylase from the gene variant ANZ105) as a processing aid

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Danisco Australia Pty Ltd to amend the Australia New Zealand Food Standards Code to permit the use of the enzyme alpha-amylase (EC 3.2.1.1) as a processing aid in starch processing to produce starch hydrolysates and in the production of potable alcohol.

On 8 January 2026, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 2 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

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## Supporting document

The following document, which informed the assessment of this application, is available on the A1305 page on the FSANZ website[2]:

Supporting Document  Risk and technical assessment report

The published submissions from the call for submissions can be found on the A1305 Consultation Hub page.

[2] A1305 Webpage - https://www.foodstandards.gov.au/food-standards-code/applications/a1305-alpha-amylase-bacillus-licheniformis-containing-gene-alpha

# Executive summary

Danisco Australia Pty Ltd[3] 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 alpha-amylase (EC 3.2.1.1) as a processing aid in starch processing to produce starch hydrolysates and in the production of potable alcohol. The enzyme is produced by *Bacillus licheniformis* containing the gene for alpha-amylase from the gene variant ANZ105.

The proposed use of this alpha-amylase is technologically justified in the quantity and form proposed by the applicant for starch processing to produce starch hydrolysates and to produce potable alcohol. The enzyme does not perform a technological function in final food and therefore functions as a processing aid for the purposes of the Code. It would have to meet relevant identity and purity specifications in the Code when added to food in accordance with the Code or sold for use in food.

FSANZ's assessment concluded there are no safety concerns with the use of alpha-amylase produced by *B. licheniformis* under the proposed conditions of use.

Following assessment, FSANZ prepared a draft variation to the Code and called for submissions on that draft on 8 January 2026. Two submissions were received in the 6-week consultation period. FSANZ has had regard to these submissions.

Based on this information and other relevant considerations outlined in this report, FSANZ has approved the draft variation proposed at the call for submissions.

The approved draft variation will amend the table to subsection S18—9(3) of the Code by listing this enzyme and its technological purpose in that table. The table to subsection S18—9(3) lists permitted processing aids and their associated technological purposes. The technological purpose of this enzyme is for use in starch processing to produce starch hydrolysates and in the production of potable alcohol. The permission will be subject to the condition that the enzyme's maximum permitted level or amount in food must be an amount consistent with Good Manufacturing Practice.

The effect of the approved draft variation will be to permit the use of this enzyme alpha-amylase (EC 3.2.1.1) from *B. licheniformis* containing the gene for alpha-amylase from the gene variant ANZ105 as a processing aid in accordance with the Code.

[3] A subsidiary of International Flavors and Fragrances Inc.

# 1 Introduction

## 1.1 The applicant

The applicant is Danisco Australia Pty Ltd – a subsidiary of International Flavors and Fragrances Inc.

## 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 alpha-amylase (EC 3.2.1.1) as a processing aid in carbohydrate processing to produce glucose syrups and other starch hydrolysates, and in the production of potable alcohol.

Although the application refers to 'carbohydrate processing,' this report uses 'starch processing' as it is the established terminology in the Code for this type of processing aid. This reflects industry practice, where the terms are often used interchangeably in the beverage industry.

The alpha-amylase in this application is produced from *Bacillus licheniformis* containing the gene for alpha-amylase from the gene variant ANZ105. This variant was developed by Danisco and is assembled from multiple bacterial alpha-amylase genes. The unique identifier ANZ105 was assigned to this alpha-amylase to ensure that any permission included in Schedule 18 only applies to the enzyme that was assessed under this application.[4]

The applicant has indicated 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)

[4] Under recent Code changes following Proposal P1055 – Definitions for gene technology and new breeding techniques, a new definition for 'genetically modified food' was adopted that excludes substances used as a processing aid. As a result of this change, enzyme processing aids produced from organisms that have been genetically modified to contain novel DNA are no longer subject to Code requirements for genetically modified food.

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.

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.

Alpha-amylase from *B. licheniformis* containing the gene for alpha-amylase from the gene variant ANZ105 is not listed in Schedule 18and 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) 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 when added to food in accordance with the Code or sold for use in food.

Subsection S3—2(1) of the Code 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 (13$^{th}$ 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

### 1.4.1 International

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 ‘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.

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.

### 1.4.2 Overseas regulations

The safety of the alpha-amylase preparation that is the subject of this application has not been directly evaluated by other regulatory agencies.

Alpha-amylase preparations from alternative production strains of *B. licheniformis* have been evaluated as safe by the European Food Safety Authority (EFSA 2024) and approved by Health Canada for use under the List of Permitted Food Enzymes (Health Canada 2018).

*B. licheniformis*, including genetically modified strains, have been approved for production of alpha-amylase in Denmark and France. The United States Food and Drug Administration (US FDA) provided a 'no questions' response to various alpha amylases from *B. licheniformis* GRAS notifications (GRN No's. 22, 24, 617, 664).

## 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 accordance with the FSANZ Act.

## 1.7 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal. The approved draft variation is at Attachment A.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

# 2 Summary of the findings

## 2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 8 January 2026. The consultation period was 6 weeks.

A total of 2 submissions were received, which are publicly available on the A1305 Consultation Hub page.

One submission from New Zealand Food Safety (NZFS) supported the proposed draft variation and did not raise any issues. The other submission from New South Wales Food Authority (NSWFA) raised minor issues. Responses to issues raised are provided in Table 1

**Table 1: Summary of issues**

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|---|---|
| The Supporting Document (SD) does not clearly identify the applicable lead specification. While the reported lead level (<5 mg/kg) meets JECFA and Food Chemicals Codex limits, compliance with the Code (section S3—4) is unclear. It is recommended that Table 1 in the SD clarify the applicable specification and the basis for acceptability where Code compliance is not demonstrated. | NSWFA | FSANZ notes the specification for lead of not more than 2 mg/kg on a dry weight basis in paragraph S3—4(a) of the Code only applies if there is no relevant specification under sections S3—2 or S3—3.<br><br>Paragraphs S3—2(1)(b) and (c) both set a relevant specification for lead of ≤ 5mg/kg.<br><br>Therefore, the specification for lead in paragraph S3—4(a) does not apply.<br><br>Section 2.2.2 and Table 1 of the SD have been amended to make it clearer which specification for lead applies to alpha-amylase. |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|---|---|
| Reference to 'ANZ105' alone may not clearly identify the specific gene variant once the Code amendment is gazetted. Consistent with precedent (Application A1269 – cell-cultured quail), it is recommended that the wording '*detailed in Application A1305*' be added to the relevant listing in the Approval Report. | NSWFA | FSANZ considers the inclusion of the wording '*detailed in application A1305*' is not necessary in this case for the following reasons:<br><br>• '*ANZ105*' is a unique identifier assigned to a single, defined gene variant assessed in Application A1305. The identifier relates specifically to the assessed gene variant.<br>• Any modification to the sequence would constitute a different gene variant and would require a separate application and safety assessment.<br><br>FSANZ further notes that the drafting approach used for application A1269 is not directly comparable for the following reasons:<br><br>• The permission for A1269 reflected the regulatory approach adopted for cell-cultured food, under which permissions are granted on a product-by-product basis following assessment of both the cell line and the associated production process.<br>• Inclusion of wording referring to "*as detailed in application A1269*" ensured that only the specific version of the cell line 221523-Fib-Quail, produced using the assessed production process and inputs, is used.<br><br>This drafting approach is not applicable to application A1305 and the permission for gene variant ANZ105. |

## 2.2 Food technology assessment

FSANZ completed a food technology assessment to determine whether the processing aid achieves its technological purpose as described in the application (see SD).

The food technology assessment concluded that the alpha-amylase performs its technological purpose in starch processing to produce starch hydrolysates and in the production of potable alcohol, after which it is inactivated, and does not perform a technological purpose in the food for sale. This enzyme therefore functions as a processing aid for the purposes of the Code.

There are relevant identity and purity specifications for the enzyme in the Code with which the enzyme will have to comply whenever it is added to food in accordance with the Code or sold for use in food

## 2.3 Risk assessment

No public health or safety concerns were identified concerning the use of the production organism, which is neither pathogenic nor toxigenic. The production strain is modified to contain the gene for alpha-amylase from the gene variant ANZ105. This variant was developed by Danisco and is assembled from multiple bacterial alpha-amylase genes. Analysis of the modified production strain confirmed the presence and stability of the inserted DNA.

No significant homology between the enzyme and any known toxins or allergens was identified. The enzyme preparation is not expected to pose a food allergenicity concern under the proposed conditions of use.

The alpha-amylase preparation is derived from the same safe strain lineage as an alpha-amylase produced by a *B. licheniformis* strain (JML-1584), previously reviewed by FSANZ as part of application A1219. The alpha-amylase from JML-1584 showed no evidence of genotoxicity *in vitro*. The no observed adverse effect level (NOAEL) in a 90-day oral gavage study in rats was 500 mg total organic solids (TOS)/kg bw/day.

The theoretical maximum daily intake (TMDI) of this alpha-amylase was calculated to be 1.15 mg TOS/kg bw/day. A comparison of the NOAEL and the TMDI results in a Margin of Exposure (MOE) of approximately 400.

Based on the reviewed data, it is concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) ‘not specified’ is appropriate.

## 2.4 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation during a period of 6 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.

The conclusions from the risk and technical assessment were that the proposed use of alpha-amylase as a processing aid is technologically justified and 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 considered it appropriate to approve the draft variation proposed following assessment (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

As stated above, FSANZ has approved a draft variation to permit the use of the enzyme as a processing aid in starch processing to produce starch hydrolysates and in the production of potable alcohol. The express permission also provides the permission for the enzyme's potential presence in the food for sale (Attachment A).

### 2.4.2 Enzyme nomenclature, source microorganism nomenclature and specifications

FSANZ notes the International Union of Biochemistry and Molecular Biology (IUBMB) lists the accepted name 'alpha-amylase' for the enzyme EC 3.2.1.1 (see section 2.1 of the SD). This is the name used in the approved draft variation.

Nomenclature for the host organism – *Bacillus licheniformis* 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 of this report). As stated above, this enzyme will have to comply with those specifications whenever it is added to food in accordance with the Code or sold for such use.

### 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 (above).

### 2.4.4 Risk management conclusion

The risk management conclusion is to permit the enzyme alpha-amylase produced by *B. licheniformis* containing the gene for alpha-amylase from the gene variant ANZ105 to be used as a processing aid in starch processing to produce starch hydrolysates and in the production of potable alcohol in accordance with the Code.

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 specific technological purposes. The maximum permitted level of the enzyme that may be present in the food would have to be an amount consistent with GMP.

## 2.5 Risk communication

### 2.5.1 Consultation

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

## 2.6 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:

### 2.6.1 Section 29

#### *2.6.1.1 Consideration of costs and benefits*

*Background to the cost and benefit analysis*

Section 29 of the FSANZ Act requires FSANZ to have regard to whether costs that would arise from a 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 the status quo is rejecting the application).

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the use of this alpha-amylase (EC 3.2.1.1) as a processing aid in starch processing to produce starch hydrolysates and in the production of potable alcohol.

A regulation impact statement (RIS) has not been prepared. FSANZ's assessment is that a RIS is not required for this application. This is on the basis that the application is minor and deregulatory in nature. It seeks to permit the use of a processing aid found to be safe and, if the draft variation concerned is approved, that use will be voluntary. This is consistent with earlier advice from the Office of Impact Analysis (OIA23-06225).

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

Industry may benefit from several improvements and efficiencies from the use of this enzyme in starch processing to produce starch hydrolysates and in the production of potable alcohol. 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.

If industry were to experience cost savings because of using this enzyme, industry may pass on some of the cost savings to consumers. Likewise, if any quality improvements are achieved (increasing product value) these may also be shared with consumers.

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.

*Conclusions from cost benefit assessment*

FSANZ has assessed that the direct and indirect benefits that would arise from permitting the proposed use of this alpha-amylase (EC 3.2.1.1) as a processing aid in starch processing to produce starch hydrolysates and in the production of potable alcohol are likely to outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

#### *2.6.1.2 Other measures*

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

#### *2.6.1.3 Any relevant New Zealand standards*

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

#### *2.6.1.4 Any other relevant matters*

Other relevant matters are considered below.

### 2.6.2. Subsection 18(1)

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

#### *2.6.2.1 Protection of public health and safety*

FSANZ undertook a risk and technical assessment and concluded there were no public health and safety concerns associated with the proposed use of this enzyme (see section 2.2 of this report and the SD).

#### *2.6.2.2 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 2.4.3 of this report.

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

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

### 2.6.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used the best available scientific evidence to conduct the risk analysis. The applicant submitted a dossier of information and scientific literature as part of their 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**

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 1.4.1 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 this 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 use of this enzyme for the applications 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 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.

[5] https://www.foodregulation.gov.au/resources/publications/policy-guideline-addition-substances-other-vitamins-and-minerals

FSANZ determined that permitting the proposed use of this enzyme as a processing aid would be consistent with these specific order policy principles for ‘technological function’. All other relevant requirements of the policy guideline would be similarly met.

## Attachments

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

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

**Food Standards (Application A1305 – Alpha-amylase from *Bacillus licheniformis* (containing the gene for alpha-amylase from the gene variant ANZ105) 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]

[To be signed by the 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 A1305 – Alpha-amylase from* Bacillus licheniformis *(containing the gene for alpha-amylase from the gene variant ANZ105) 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:

| | | |
|---|---|---|
| α-Amylase (EC 3.2.1.1) sourced from *Bacillus licheniformis* containing the gene for α-amylase from the gene variant ANZ105 | For use in:<br>(a) starch processing to produce starch hydrolysates; and<br>(b) the production of potable alcohol. | GMP |

# Attachment B – Explanatory Statement

## EXPLANATORY STATEMENT

*Food Standards Australia New Zealand Act 1991*

***Food Standards (Application A1305 – Alpha-amylase from* Bacillus licheniformis *(containing the gene for alpha-amylase from the gene variant ANZ105) 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 A1305, which sought to amend the Code to permit the use of the enzyme alpha-amylase (EC 3.2.1.1), from *Bacillus licheniformis* containing the gene for alpha-amylase from the gene variant ANZ105, as a processing aid for use in starch processing to produce starch hydrolysates and in the production of potable alcohol.

The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards* (*Application A1305 – Alpha-amylase from* Bacillus licheniformis *(containing the gene for alpha-amylase from the gene variant ANZ105, 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 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 alpha-amylase (EC 3.2.1.1) sourced from *Bacillus licheniformis* containing the gene for alpha-amylase from the gene variant ANZ105 as a processing aid in starch processing to produce starch hydrolysates and the production of potable alcohol. 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 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 A1305 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 8 January 2026 for a 6-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

A regulation impact statement (RIS) was not prepared. FSANZ's assessment is that a RIS is not required for this application. This is on the basis that the application is 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 earlier advice from the Office of Impact Analysis (OIA23-06225)[6].

[6] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au).

## 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 A1305 – Alpha-amylase from* Bacillus licheniformis *(containing the gene for alpha-amylase from the gene variant ANZ105) as a processing aid) Variation*.

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

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

***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:

- 'α-Amylase (EC 3.2.1.1) sourced from *Bacillus licheniformis* containing the gene for alpha-amylase from the gene variant ANZ105'

The permitted technological purpose for this enzyme is prescribed in column 2 of the table i.e. for use in starch processing to produce starch hydrolysates, and the production of potable alcohol.

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 approved draft variation permits the use of the enzyme alpha-amylase (EC 3.2.1.1) from *Bacillus licheniformis* containing the gene for alpha-amylase from the gene variant ANZ105 as a processing aid in accordance with the Code.