



4 November 2022

[219-22]

Approval report – Application A1219

Alpha-amylase from GM *Bacillus licheniformis* as a processing aid

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Danisco New Zealand Limited to amend the Australia New Zealand Food Standards Code to permit the use of the enzyme alpha-amylase from a genetically modified *Bacillus licheniformis* containing the alpha-amylase gene from *Cytophaga* species, to be used as a processing aid in brewed beverages, potable alcohol production and starch processing.

On 16 June 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ did not receive any submissions during the consultation period.

FSANZ approved the draft variation on 26 October 2022. The Food Ministers' Meeting¹ was notified of FSANZ's decision on 4 November 2022.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

¹ Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation.

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Supporting document

The [following document](#) which informed the assessment of this Application is available on the FSANZ website:

SD Risk and Technical Assessment

Executive summary

Danisco New Zealand Ltd 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) from genetically modified (GM) *Bacillus licheniformis* as a processing aid for use in brewing, potable alcohol production and starch processing. The alpha-amylase enzyme is produced by submerged fermentation of *B. licheniformis* carrying the alpha-amylase gene from *Cytophaga* species (sp.).

FSANZ undertook an assessment to determine whether the enzyme achieves the requested technological purpose in the quantity and form proposed to be used, and to evaluate public health and safety concerns associated with its use.

FSANZ concluded that the proposed use of the alpha-amylase enzyme in the brewing of beverages, production of potable alcohol and starch processing is consistent with its typical function of catalysing the breakdown of starch to sugars. Analysis of the evidence provides adequate assurance that the use of the enzyme, in the form and requested amount (i.e. at a level not higher than necessary to achieve the desired enzyme reaction according to Good Manufacturing Practice (GMP)), is technologically justified and has been demonstrated to be effective in achieving the stated purpose.

Alpha-amylase performs its technological purpose during the production of the nominated foods and is not performing a technological purpose in the final food, therefore functioning as a processing aid for the purposes of the Code. Relevant identity and purity specifications for the enzyme are included in the Code.

No public health and safety concerns were identified in the assessment of alpha-amylase from GM *B. licheniformis* under the proposed conditions of use. A microbiological assessment concluded that *B. licheniformis* has a long history of safe use in food and is neither pathogenic nor toxigenic. A biotechnology assessment confirmed the genetic modification is as described and that the inserted gene has been stably introduced. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use. 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, FSANZ called for submissions regarding the draft variation from 16 June to 28 July 2022. FSANZ did not receive any submissions for this application during that period.

Based on the information above and on other relevant considerations 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 enzyme alpha-amylase (EC 3.2.1.1) sourced from *B. licheniformis* containing the alpha-amylase gene from *Cytophaga* sp. as a permitted processing aid. The enzyme would be permitted for use in brewing, the production of potable alcohol and starch processing. This permission is subject to the condition that the maximum permitted level of the enzyme used 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

The applicant is Danisco New Zealand Ltd (Danisco).

1.2 The Application

The applicant is seeking 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) from genetically modified (GM) *Bacillus licheniformis* (*B. licheniformis*) as a processing aid. The alpha-amylase enzyme is produced by submerged fermentation of *B. licheniformis* carrying the alpha-amylase gene from *Cytophaga* species (sp.). The stated purpose is for use during the processing of brewed beverages, potable alcohol production and starch processing.

The applicant markets different liquid preparations containing this enzyme as the active component under various names including 'Spezyme SL' and 'GC 126' in other countries where its use is permitted (see Section 2.4.3 of this report).

The applicant has indicated the enzyme is to be used in accordance with Good Manufacturing Practice (GMP) i.e. the minimum amount is used to achieve the technological purpose.

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

Enzymes used to process and manufacture food are considered processing aids. Although they may be present in the final food, they no longer provide a technological purpose in the final food.

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a processing aid' unless that substance's use as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance 'used as a processing aid' in relation to a food is a substance used during the course of processing that meets all of the following conditions:

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale, and
- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

Standard 1.3.3 and Schedule 18 of the Code list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. The table to subsection S18—9(3) lists those substances, including enzymes derived from

particular sources, that are permitted to be used as processing aids for specific technological purposes in relation to:

- if a food is specified—that food; or
- 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).

Alpha-amylase is already permitted to be used as a processing aid by the Code including from plant sources (malted cereals (subsection S18—4(4)), and from various microbial origins including *B. licheniformis* (subsections S18—4(5) and S18—9(3)), however not from *B. licheniformis* carrying the alpha-amylase gene from *Cytophaga* sp. 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 (2020) Food Chemicals Codex (12th 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 imposed by the Code for that food.

Subsection 1.2.3—4(1) requires certain foods (e.g. allergens) or their derivatives (as listed in the table to section S9—3 of Schedule 9) to be declared when present in a food for sale (unless they are exempt under subsection 1.2.3—4(4)). These certain foods may be present in a processing aid (paragraph 1.2.3—4(5)(c)). Where the food to be declared is present in a processing aid, subsection 1.2.3—6(2) requires a declaration (as per paragraph 1.2.1—8(1)(d) or subparagraph 1.2.4—5(6)(b)(i)) to be made by (among other things) listing in the statement of ingredients of the food for sale the required name² of the food to be declared and the words 'processing aid' in conjunction with that required name³. If the food is not required to bear a label, the declaration must be displayed in connection with the display of the food or provided to the purchaser on request (subsections 1.2.1—9(6) and (7)).

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

³ On 25 February 2021 new requirements for the labelling of allergens were introduced in the Code and suppliers have until 25 February 2024 to change over to these new requirements. If a food was packaged and labelled before 25 February 2024 and it complied with the previous allergen labelling requirements, then that food can remain on sale for another two years as long as it complies with the rest of 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 requires processing aids that are, or have as ingredients, foods produced using gene technology to be labelled 'genetically modified' in conjunction with the name of that food, where novel DNA and/or novel protein from the processing aid remains present in the final food. The requirement applies to foods for sale that consist of or have as an ingredient, food that is a *genetically modified food*⁴ (GM food). The requirements imposed by section 1.5.2—4 apply only to foods for sale prescribed by Divisions 2 to 4 of Standard 1.2.1.

1.4 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). In contrast to food additives, there is no Codex 'general standard' for enzymes, however as noted above, there are internationally recognised identity and purity specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

In addition, the *Codex Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010) set out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP.

1.5 Reasons for accepting Application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), and
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application is being assessed under the General Procedure in the FSANZ Act.

1.7 Decision

For reasons set out 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, potable alcohol production and starch processing.

The draft variation as proposed following assessment was approved with amendments. The amendments made to the draft variation are explained in Section 2.3.2 of this report.

The variation takes effect on gazettal. The approved draft variation is at Attachment A.

⁴ 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*).

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

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

2 Summary of the findings

2.1 Submissions

FSANZ sought public comments on the draft variation included in the call for submissions report between 16 June and 28 July 2022. FSANZ did not receive any submissions during that period.

2.2 Risk assessment

FSANZ has assessed the public health and safety risks associated with alpha-amylase from *Cytophaga* sp. that is produced by GM *B. licheniformis* and its proposed use as a processing aid. A summary of this risk assessment is provided below.

A technical assessment concluded that the proposed use of this alpha-amylase as a processing aid in starch processing, brewing of beverages and production of potable alcohol is technologically justified.

No public health and safety concerns were identified in the assessment of alpha-amylase from GM *B. licheniformis* under the proposed conditions of use. A microbiological assessment concluded that *B. licheniformis* has a long history of safe use in food and is neither pathogenic nor toxigenic. A biotechnology assessment confirmed the genetic modification is as described and that the inserted gene has been stably introduced. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use.

In the absence of any identifiable hazard, an acceptable daily intake (ADI) 'not specified' is appropriate.

For further details on the risk assessment, refer to SD – Risk and Technical Assessment.

2.3 Risk management

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

The conclusions from the risk and technical assessment were that the proposed use of the enzyme is technically justified and there were no safety concerns associated with its proposed use.

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, FSANZ considers it appropriate to approve the draft variation proposed following assessment (Attachment A), with amendments as explained in Section 2.3.2.

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

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

The express permission for the enzyme to be used as a processing aid will also provide 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)⁵.

2.3.2 Enzyme nomenclature, source microorganism nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name 'α-amylase'. This is the name used in the draft variation and the name used in existing permissions for alpha-amylase in Schedule 18. The word 'alpha' has been used in this report and was used by the applicant in the application, instead of its symbol. The second reference to 'α-Amylase' in the draft variation proposed at the call for submissions has been amended to 'α-amylase' with a lower case 'a' in the approved draft variation, to correct the use of capital and lower-case letters in that sentence.

Nomenclature for the host and gene donor organisms (*Bacillus licheniformis* and *Cytophaga* species, respectively) is in accordance with accepted international norms. The approved draft variation refers to *Cytophaga* species rather than a specific species as would normally be included in Schedule 18, because in this case systematic microbiological classification of the species of *Cytophaga* is incomplete (see Section 3.1.2 of the SD). The reference to 'a *Cytophaga* species' in the draft variation proposed at the call for submissions has been amended to '*Cytophaga* species' (omission of 'a') in the approved draft variation. This is to clarify that the permission is not limited to a particular *Cytophaga* species.

There are relevant identity and purity specifications for the enzyme in two of the primary sources of specifications listed in Schedule 3 of the Code – namely the JECFA Combined Compendium of Food Additive Specifications, and the United States Pharmacopeial Convention Food Chemicals Codex (refer to Section 1.3.2 above).

2.3.3 Labelling

In general, processing aids are exempt from the requirement to be declared in the statement of ingredients, unless other labelling requirements apply (see Section 1.3.3 above). In the case of foods manufactured using this processing aid, other requirements will apply as detailed in Sections 2.3.3.1 and 2.3.3.2 below.

2.3.3.1 Declaration of certain foods

Section 2.2.1 of SD1 states that wheat and soybeans could be present in the enzyme concentrate. If wheat, gluten or soy is present in a food for sale, including when present as a

⁵ 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'.

processing aid or an ingredient or component of a processing aid, they must be declared unless an exemption applies e.g. alcohol distilled from wheat (see subsection 1.2.3—4(4) of Standard 1.2.3 and the table to section S9—3).

2.3.3.2 Labelling requirements for food produced using gene technology

Section 1.5.2—4 of the Code generally requires a food for sale that consists of a GM food or has a GM food as an ingredient to be labelled as ‘genetically modified’, unless one of the exemptions listed in that subsection apply. If the GM food is present in the food for sale as an ingredient due to its use as a processing aid, the ‘genetically modified’ statement must be in conjunction with the name of the GM food (subsection 1.5.2—4(2)) and it may be included in the statement of ingredients for the food for sale (subsection 1.5.2—4(3)).

2.3.4 Risk management conclusion

The risk management conclusion is to permit the enzyme, alpha-amylase (EC 3.2.1.1) sourced from a GM *B. licheniformis* containing the alpha-amylase gene from *Cytophaga* sp., 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 use as a processing aid in brewing, the production of potable alcohol and starch processing. The maximum level at which the enzyme may be present in the food will 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 will 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

Consultation is a key part of FSANZ’s standards development process.

FSANZ developed and applied a standard communication strategy to this application. The call for submissions was notified via the Food Standards Notification Circular, media release, FSANZ’s social media tools and Food Standards News.

The process by which FSANZ approaches standards’ development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

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 Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to processing aids and GM food (OBPR correspondence dated 24 November 2010, 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 considered permitting the proposed use of the enzyme alpha-amylase from a GM *B. licheniformis* as a processing aid in brewed beverages, potable alcohol production and starch processing.

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 seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the proposed use of the enzyme produced from the GM *B. licheniformis*.

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

2.5.1.1.1 Costs and benefits of permitting the use of enzyme alpha-amylase (EC 3.2.1.1) sourced from a GM B. licheniformis as a processing aid

Industry

The enzyme alpha-amylase is already available to industry from other production sources. Due to the voluntary nature of the proposed permission, industry will use alpha-amylase from this additional source, GM *B. licheniformis*, where businesses in the industry believe a net benefit exists for them. An additional source of this enzyme may help industry save on production costs of brewing, production of potable alcohol and starch processing.

The use of this enzyme from this source has GRAS status in USA and approval for various purposes in France and Denmark. Therefore, the approval of this enzyme in the Code may help some of Australia's and New Zealand's sales in international markets. There may, however, be more competing imports in the domestic market from countries that use this enzyme into the future.

Consumers

Industry may pass cost savings to consumers, where it is cheaper to source alpha-amylase from GM *B. licheniformis* in production processes.

Government

Permitting the enzyme alpha-amylase from this additional source may result in a small cost to government in terms of adding this enzyme to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment at the call for submissions stage was that the direct and indirect

benefits that would arise from permitting the proposed use of the enzyme alpha-amylase from a GM *B. licheniformis* as a processing aid in brewing, potable alcohol production and starch processing 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 SD) and concluded there were no public health and safety concerns associated with the proposed use of this enzyme.

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

The labelling requirements 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 technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in the SD.

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

There are relevant international specifications for enzyme preparations, 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 the substance is currently approved for use as a processing aid in France and Denmark. Approval for its use will bring Australia and New Zealand into line with other jurisdictions where it is already authorised for use. In this way, Australia and New Zealand would 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 this 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 the various applications proposed by the applicant.

Ultimately, the domestic food industry will make their own economic decisions, taking into account the costs and benefits of using the new enzyme, to determine if it is of benefit to their particular business.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

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

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*⁶ 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 has 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

⁶ [Food regulation website](#)

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



Food Standards (Application A1219 – Alpha-amylase from GM *Bacillus licheniformis* as a processing aid) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name and position title]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1219 – Alpha-amylase from GM Bacillus licheniformis 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 <i>Bacillus licheniformis</i> containing the α -amylase gene from <i>Cytophaga</i> species	For use in:	GMP
	(a) brewing;	
	(b) the production of potable alcohol; and	
	(c) starch processing.	

Attachment B – Explanatory Statement

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 A1219 which sought an amendment to the Code to permit the enzyme, alpha-amylase from a genetically modified *Bacillus licheniformis* containing the alpha-amylase gene from *Cytophaga* species, to be used as a processing aid in brewing, potable alcohol production and starch processing. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a 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 standard or draft variation of a standard.

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 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 prepared 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 alpha-amylase gene from *Cytophaga* species, as a processing aid for use in brewing, the production of potable alcohol and starch processing. This permission is subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with Good Manufacturing Practice (GMP).

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019)) and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition). 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 A1219 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 16 June 2022 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting new processing aids and genetically modified food (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting new genetically modified 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.

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 draft variation [inserts a new entry, in alphabetical order, into the table to subsection S18—9(3). 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 α-amylase gene from *Cytophaga* species'.

The International Union of Biochemistry and Molecular Biology uses the accepted name 'α-

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amylase'. This is the name used in the draft variation, which is also consistent with the name used in existing permissions for alpha-amylase in Schedule 18. However, the word 'alpha' is used in this Explanatory Statement, instead of its symbol.

The technological purpose for this enzyme prescribed in column 2 of the table is for use as a processing aid in brewing, the production of potable alcohol and starch processing.

Specifically, this enzyme catalyses the breakdown of starch to sugars in these processes.

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 variation is to permit the proposed use of the enzyme alpha-amylase (EC 3.2.1.1), sourced from *Bacillus licheniformis* containing the alpha-amylase gene from *Cytophaga* species, 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 (Application A1219 – Alpha-amylase from GM *Bacillus licheniformis* as a processing aid) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name and position title]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1219 – Alpha-amylase from GM Bacillus licheniformis 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 <i>Bacillus licheniformis</i> containing the α -Amylase gene from a <i>Cytophaga</i> species	For use in:	GMP
	(a) brewing;	
	(b) the production of potable alcohol; and	
	(c) starch processing.	