

21 March 2022
194-22

Approval report – Application A1231

Maltogenic alpha amylase from GM *Escherichia coli* as a processing aid (enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Advanced Enzyme Technologies Ltd. to approve the use of a maltogenic alpha amylase (EC 3.2.1.133), sourced from a genetically modified (GM) strain of *Escherichia coli*, as a processing aid in baking, brewing and starch processing.

On 30 November 2021, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 7 March 2022. The Food Minister's Meeting¹ was notified of FSANZ's decision on 21 March 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 the Australia and New Zealand Ministerial Forum on Food Regulation.

Table of contents

EXECUTIVE SUMMARY	3
1 INTRODUCTION	4
1.1 THE APPLICANT	4
1.2 THE APPLICATION	4
1.3 THE CURRENT STANDARD	4
1.3.1 <i>Permitted use</i>	4
1.3.2 <i>Identity and purity requirements</i>	5
1.3.3 <i>Labelling requirements</i>	5
1.4 INTERNATIONAL STANDARDS	6
1.5 OVERSEAS APPROVALS	6
1.6 REASONS FOR ACCEPTING APPLICATION	6
1.7 PROCEDURE FOR ASSESSMENT	6
1.8 DECISION	6
2 SUMMARY OF THE FINDINGS	7
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	7
2.2 RISK ASSESSMENT	7
2.3 RISK MANAGEMENT	8
2.4 RISK COMMUNICATION	9
2.4.1 <i>Consultation</i>	9
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS	9
2.5.1 <i>Section 29</i>	9
2.5.2 <i>Subsection 18(1)</i>	11
3 REFERENCES	12
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE	13
ATTACHMENT B – EXPLANATORY STATEMENT	15

Supporting document

The [following document](#)¹ which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report

¹ [https://www.foodstandards.gov.au/code/applications/Pages/A1231---Maltogenic-alpha-amylase-from-GM-Escherichia-coli-as-a-processing-aid-\(enzyme\).aspx](https://www.foodstandards.gov.au/code/applications/Pages/A1231---Maltogenic-alpha-amylase-from-GM-Escherichia-coli-as-a-processing-aid-(enzyme).aspx)

Executive summary

Advanced Enzyme Technologies Ltd applied to Food Standards Australia New Zealand (FSANZ) to permit use of the enzyme maltogenic alpha amylase (EC 3.2.1.133) derived from a new source – a genetically modified (GM) strain of *Escherichia coli*² (*E. coli*), expressing a maltogenic alpha amylase gene from *Geobacillus stearothermophilus*. Permission was sought for use as a processing aid in baking, brewing and starch processing.

Enzymes used to produce and manufacture food are considered processing aids and are regulated by the Australia New Zealand Food Standards Code (the Code). The table to subsection S18—9(3) of Schedule 18 in the Code lists substances (including enzymes) permitted to be used as processing aids for specific technological purposes. Maltogenic alpha amylase sourced from this GM strain of *E. coli* is not currently permitted to be used as a processing aid.

The stated technological purpose of this enzyme is for use as a processing aid in baking, brewing and starch processing. The evidence presented to support the proposed use of this enzyme provides adequate assurance that the enzyme is technologically justified and has been demonstrated to be effective in achieving its stated purpose. This enzyme meets international purity specifications.

After undertaking its risk and technical assessment, FSANZ concluded that there are no public health and safety concerns with the use of this enzyme under the proposed use conditions.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 30 November 2021 to 18 January 2022. Two submissions were received in response. Both submissions were supportive of the draft variation.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation to subsection S18—9(3) of the Code listing the enzyme, maltogenic alpha amylase (EC 3.2.1.133) sourced from *E. coli* containing the maltogenic α -amylase gene from *G. stearothermophilus* as a permitted processing aid in that table. The technological purpose of this enzyme is use as a processing aid in baking, brewing and starch processing. The permission is subject to the condition that the amount of the enzyme used must be consistent with Good Manufacturing Practice (GMP). The effect of the approved draft variation is to permit the proposed use of this enzyme as a processing aid in accordance with the Code.

² The applicant has designated this genetically modified *E. coli* strain as *E. coli* BLASC and this is why it has sometimes been referred to as *E. coli* BLASC in SD1 and this Approval Report.

1 Introduction

1.1 The applicant

Advanced Enzyme Technologies Ltd, based in India, is a manufacturer and marketer of enzymes and probiotics.

1.2 The application

The applicant sought to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme maltogenic³ alpha amylase (EC 3.2.1.133), sourced from a genetically modified (GM) strain of *Escherichia coli* (*E. coli*) expressing a maltogenic alpha amylase gene from *Geobacillus stearothermophilus*, as a processing aid in baking, brewing and starch processing.

The technological purpose of the processing aid is to hydrolyse the (1→4)-alpha-D-glucosidic linkages in starch polysaccharides to produce maltose (composed of two glucose units) and maltotriose (composed of three glucose units) as the main hydrolysis products. The applicant claims various benefits of using this enzyme including:

- during baking, the enzyme produces selective hydrolysis of starch that helps prevent retrogradation of starch in baked products, thus improving their shelf life, and providing positive effects on sensory qualities of baked products including crumb softness, resilience, loaf volume and texture
- in starch processing, the enzyme hydrolyses 1,4-oligosachharide links to yield the desired product, this being maltose/glucose syrup
- in brewing, the enzyme hydrolyses the starch containing substrates to produce simple sugars that support yeast growth during fermentation, resulting in better yields of alcohol.

The enzyme will be used as a processing aid whereby it performs its primary technological function during food processing. Use levels will be consistent with Good Manufacturing Practice (GMP), which limits the amount of the enzyme that is added to food to the lowest possible level necessary to accomplish its desired effect.

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 in the Code 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

³ The term 'maltogenic' refers to the enzyme's ability to break down starch into maltose.

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 relevant 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 of a food produced using gene technology as an ingredient or component in a food for sale 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).

There is currently a permission for maltogenic alpha amylase (EC 3.2.1.133) derived from a different source in the table to subsection S18—4(5), to be used in the manufacture of any foods. There is also a permission for a maltogenic alpha amylase derived from a different microbial source within the table to subsection S18—9(3), for use in the manufacture of bakery products. However, maltogenic alpha amylase from the particular microbial source requested in this application is not currently permitted.

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 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 Food Chemicals Codex (12th edition, 2020). Certain earlier publications from these primary sources include the relevant specifications for enzyme preparations used in food processing (JECFA (2006) and FCC (2008), respectively).

1.3.3 Labelling requirements

Paragraph 1.1.1—10(8) of the Code provides that a 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 to be declared when present in a food for sale. Paragraph 1.2.3—4(5)(c) states the food may be present as a substance used as a processing aid, or an ingredient or component of such a substance.

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', 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 generally apply only to foods for retail sale and to foods sold to a caterer under subsections 1.2.1—8(1) and 1.2.1—9(3), and section 1.2.1—15, respectively.

1.4 International standards

The Codex Alimentarius does not establish standards for processing aids or for enzymes. Individual countries regulate the use of enzymes differently to the Code. However, there are internationally recognised specifications for enzymes established by JECFA and Food Chemicals Codex, as outlined in Section 1.3.2 above.

1.5 Overseas approvals

[Regulation \(EC\) No 1332/2008](#) (the Regulation) harmonises the rules for food enzymes in the European Union (EU). Previous to the Regulation, food enzymes used as processing aids were not regulated at the EU level. According to the Regulation, all food enzymes currently on the EU market, as well as new food enzymes, are subject to a safety evaluation by the European Food Safety Authority (EFSA). Where appropriate, they are approved by the European Commission by means of an EU list. Currently, there is no EU list of authorised food enzymes. Until the establishment of such a list, EU Member States' legislation applies.

Notwithstanding the above, the applicant provided an EFSA safety evaluation on maltogenic alpha amylase produced using *E. coli* BLASC. EFSA concluded that, under the intended conditions of use, the evaluated food enzyme does not raise safety concerns and that the allergenic risk was likely to be low.

1.6 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.

1.7 Procedure for assessment

The application was assessed under the General Procedure in the FSANZ Act.

1.8 Decision

For reasons set out in this report, FSANZ decided to approve a draft variation permitting the use of this enzyme as a processing aid in baking, brewing and starch processing, as requested by the applicant.

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 draft variation as proposed following assessment was approved without change. The variation takes effect on the date of 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 draft variation to the Code from 30 November 2021 to 18 January 2022. Two submissions were received, both from government agencies, and both supported the application and draft variation (see Table 1).

Table 1: Summary of submitters comments

Submitter	Comments
New Zealand Food Safety	Supports amending the Code to permit use of the enzyme.
Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions	Supports progression of the application.

2.2 Risk assessment

FSANZ assessed the public health and safety risks associated with the use of maltogenic alpha amylase (EC 3.2.1.133), sourced from a GM strain of *E. coli* (*E. coli* BLASC), as a processing aid in baking, brewing and starch processing (see SD1). A summary of this risk assessment is provided below.

No public health and safety concerns were identified in the assessment of this enzyme under the proposed use conditions. The *E. coli* host is neither pathogenic nor toxigenic and analysis of the GM production strain (*E. coli* BLASC) confirmed the presence and stability of the introduced DNA.

Maltogenic alpha amylase was not genotoxic *in vitro*. The no observed adverse effect level (NOAEL) determined in a 90-day oral gavage study in rats was 1000 mg/kg bw/day total protein, equivalent to 838 mg/kg bw/day Total Organic Solids (TOS). The theoretical maximum daily intake (TMDI) was calculated to be 1.06 mg/kg bw/day TOS. A comparison of the NOAEL and the TMDI gives a Margin of Exposure (MOE) of approximately 790.

Bioinformatic analysis indicated that the enzyme:

- shows no significant homology with any known toxins
- has a degree of homology with several known allergens. None were food allergens.

No report of sensitisation to any form of maltogenic alpha amylases was found in a search of the scientific literature and maltogenic alpha amylases from the same source organism are already permitted in the Code. On that basis, FSANZ determined that this enzyme is unlikely to pose an allergen risk to consumers when used as a processing aid in food.

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

2.3 Risk management

2.3.1 Regulatory approval for processing aids

As outlined above, FSANZ concluded that there are no public health and safety concerns relating to the proposed use of this maltogenic alpha amylase (EC 3.2.1.133) sourced from a genetically modified strain of *E. coli* as a processing aid.

From the food technology assessment, FSANZ concluded that use of this enzyme in baking, brewing and starch processing is consistent with its typical function of starch hydrolysis. Analysis of the evidence provided adequate assurance that the enzyme's use in the quantity and form proposed, which must be consistent with GMP controls and processes, is technologically justified. The enzyme meets international purity specifications.

This enzyme maltogenic alpha amylase performs its primary technological purpose during food processing and does not perform a technological purpose in the final food, therefore functioning as a processing aid as defined in the Code.

FSANZ therefore considered it appropriate to permit the use of the enzyme maltogenic alpha amylase (EC 3.2.1.133) sourced from a genetically modified strain of *E. coli* as a processing aid in baking, brewing and starch processing. The permission is subject to the condition that the maximum permitted level of this enzyme used in food processing is consistent with GMP.

A draft variation to the Code has been prepared to permit the proposed use of this enzyme (Attachment A). There are relevant identity and purity specifications for the enzyme in Schedule 3 of the Code with which the enzyme must comply.

The express permission for the enzyme to be used as a processing aid would also provide the permission for its potential presence in the food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology for Code purposes 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

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name 'glucan 1,4- α -maltohydrolase' for the enzyme with an EC number of EC 3.2.1.133. However, FSANZ decided to use the name 'maltogenic α -amylase', which the IUBMB lists as one of the 'other' names for this enzyme, in the approved draft variation to the Code, to remain consistent with how the already permitted maltogenic alpha amylases have been listed in the Code. A variation of this name i.e. 'maltogenic **alpha** amylase' was used throughout the application and, as such, is used in this document and SD1.

2.3.2 Labelling requirements

The generic exemption from listing processing aids in the statement of ingredients would apply to foods manufactured using this enzyme processing aid (see Section 1.3 above).

2.3.2.1 Labelling requirements for food produced using gene technology

Standard 1.5.2 in effect provides that a substance used as a processing aid that contains novel DNA or novel protein is a GM food. In contrast to the generic exemption for listing processing aids, subsection 1.5.2—4(2) states that the information relating to foods produced

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'.

using gene technology must include the statement 'genetically modified' in conjunction with the name of the GM food. Subsection 1.5.2—4(3) states that if the GM food is used as a processing aid, the information may be included in the statement of ingredients.

The requirement for labelling as 'genetically modified' differs depending on whether the GM food is an ingredient of the food for sale or not. A food for retail sale or sold to a caterer that contains the enzyme maltogenic alpha amylase sourced from this GM *E. coli* strain as an ingredient (e.g. the enzyme is used in the manufacture of bread) would be required to be labelled 'genetically modified' in conjunction with the name of the enzyme.

FSANZ notes however if the food made using the enzyme (e.g. bread) is not a food for sale itself (e.g. an ingredient in a mixed food such as a crumb coating on frozen fish fillets), the enzyme would not be an ingredient in the food for sale. Therefore, the requirement to label this maltogenic alpha amylase as 'genetically modified' would not apply in this case, because the labelling requirements only apply to food for sale that consists of, or has as an ingredient, a GM food (section 1.5.2—4(1)).

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 tools and Food Standards News.

The process by which FSANZ considers 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.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. All comments are valued and contribute to the rigour of our assessment.

The draft variation was considered for approval by FSANZ having regard to all submissions made during the call for submissions period.

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of 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 genetically modified 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 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 (i.e. rejecting the application). This analysis considered permitting the use of maltogenic alpha amylase derived from a new source, i.e., from GM *E. coli* containing the maltogenic α -amylase gene from *G. stearothermophilus* (the enzyme), as a processing aid for baking, brewing and starch processing.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting the use of the enzyme.

Costs and benefits of permitting the use of enzyme maltogenic alpha amylase (EC 3.2.1.133) sourced from a GM strain of E. coli as a processing aid (the new enzyme source)

Using the enzyme from this new permitted production microorganism may benefit industry by having additional choice of inputs to their manufacturing process especially if it proves cheaper, is more effective than what is presently available or results in additional competition. Due to the voluntary nature of the permission, manufacturers would only use it where they believe a net benefit exists for them. Part of savings to the manufacturing industry may be passed on to consumers. Consumers may conceivably also as a result of its use have access to higher quality products.

Permitting the enzyme to be used as a processing aid may result in a small cost to government in terms of adding this new substance 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 was that the direct and indirect benefits that would arise from permitting the use of the new enzyme source in question most likely outweigh the associated costs. No further information was received during the consultation process that changed the findings from the analysis of costs and benefits in the call for submissions.

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 which are relevant to the permitted use of the enzyme processing aid in question 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 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 (SD1) and concluded that there were no public health and safety concerns relating to the use of the enzyme.

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

Existing labelling requirements in the Code related to the enzyme are discussed in Section 2.3.2 of the report above.

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

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

There are no Codex Alimentarius Standards for processing aids or enzymes. However, the enzyme processing aid meets the general specifications for enzymes set out in the JECFA Combined Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes referred to in Section 1.3 of this report.

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

The maltogenic alpha amylase from the strain *E. coli* BLASC was evaluated by EFSA in 2019 and it was determined that the enzyme does not raise safety concerns under the intended conditions of use (EFSA 2019). Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with other countries overseas. In this way, Australia and New Zealand will be able to remain competitive with international markets.

The conclusion of the risk assessment was that there were no public health and safety concerns associated with the production microorganism or with using the enzyme as a food processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from this alternative enzyme for 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 Forum on Food Regulation**

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 determined that permitting the use of this enzyme as a processing aid is consistent with the specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

3 References

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (2019) Safety evaluation of the food enzyme maltogenic amylase from genetically modified *Escherichia coli* (strain BLASC). EFSA J. 2019; 17(5):5769.

FAO/WHO (2006) Combined compendium of food additive specifications, Food and Agriculture Organization of the United Nations, Rome. <http://www.fao.org/docrep/009/a0691e/A0691E03.htm>

IUBMB (2021) EC 3.2.1.133. <https://iubmb.qmul.ac.uk/enzyme/EC3/2/1/133.html>

The United States Pharmacopeia (2020) Food Chemicals Codex 12th Edition, United States Pharmacopeial Convention, Rockville, MD. <http://publications.usp.org/>

Attachments

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

⁶ Available on the [Food regulation website](#) (accessed 18 January 2022).

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



Food Standards (Application A1231 – Maltogenic alpha amylase from GM *Escherichia coli*) 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]

[Delegate's name and position]

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 A1231 – Maltogenic alpha amylase from GM Escherichia coli) 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:

Maltogenic α -Amylase (EC 3.2.1.133) sourced from <i>Escherichia coli</i> containing the maltogenic α -Amylase gene from <i>Geobacillus stearothermophilus</i>	For use in baking, brewing and starch processing	GMP
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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 A1231 which sought permission to use the enzyme maltogenic alpha amylase (EC 3.2.1.133) sourced from a genetically modified (GM) strain of *Escherichia coli* (*E. coli*), expressing a maltogenic alpha amylase gene from *Geobacillus stearothermophilus*, as a processing aid in baking, brewing 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' Meeting⁷, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a draft variation amending the table to section S18—9(3) of the Code to permit the use of the enzyme, maltogenic alpha amylase (EC 3.2.1.133) sourced from a GM strain of *E. coli* expressing a maltogenic alpha amylase gene from *Geobacillus stearothermophilus*, as a processing aid in baking, brewing and starch processing, subject to the condition that the amount of enzyme used must be consistent with good manufacturing practice (GMP).

The Authority noted that the International Union of Biochemistry and Molecular Biology uses the 'accepted' name 'glucan 1,4- α -maltohydrolase' for this enzyme. However, the Authority decided to use the alternative name 'maltogenic α -amylase' in the variation to the Code, to remain consistent with how the already permitted maltogenic alpha amylases have been listed in the Code. A variation of this name i.e. 'maltogenic alpha amylase' was used throughout the application and, as such, this document.

3. 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

⁷ Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation.

Schedule 3. 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/WHO 2019) and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition). These include specifications for enzyme preparations used in food processing.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1231 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 30 November 2021 for a seven-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 (RIS) for applications relating to 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 is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

5. 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 94 of the FSANZ Act.

6. Variation

Item [1] of the variation inserts in the table to subsection S18—9(3) a new entry for "Maltogenic α -Amylase (EC 3.2.1.133) sourced from *Escherichia coli* containing the maltogenic α -Amylase gene from *Geobacillus stearothermophilus*" into column 1, and "For use in baking, brewing and starch processing" into column 2, and "GMP" into column 3.

The new entry, in effect, permits the use of the enzyme, maltogenic alpha amylase (EC number 3.2.1.133), sourced from *E. coli* containing the maltogenic alpha amylase gene from *G. stearothermophilus*, as a processing aid for a specific technological purpose. The permitted technological purpose for this enzyme is use as a processing aid in baking, brewing and starch processing.

The permission is subject to the condition that the maximum permitted level or amount of this enzyme that may be used in food processing must be consistent with GMP.