

30 November 2021
181-21

Call for submissions – 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 maltogenic alpha amylase, sourced from GM *Escherichia coli*, as a processing aid in baking, brewing and starch processing and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 18 January 2022

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au. Hard copy submissions may be sent to one of the following addresses:

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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), sourced from a genetically modified (GM) strain of *Escherichia coli*, as a processing aid in baking, brewing and starch processing. In effect, this application seeks permission for an alternative source to an already permitted enzyme.

Maltogenic alpha amylase catalyses the hydrolysis of (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 advises that this enzyme is of use in various applications. Specifically, in baking, the selective hydrolysis of starch helps prevent retrogradation of starch in baked products, which improves their shelf life, and also has a positive effect on sensory properties. In starch processing, the enzyme hydrolyses 1,4-oligosachharide links to predominantly 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.

The maltogenic alpha amylase in this application is produced by a GM strain of *E. coli* (*E. coli* BLASC) expressing a maltogenic alpha amylase gene from *Geobacillus stearothermophilus*. The *E. coli* BLASC host is neither toxigenic nor pathogenic and analysis of the GM production strain confirmed presence and stability of the introduced DNA.

The enzyme showed no evidence of genotoxicity in vitro. Bioinformatic analysis indicated that the enzyme shows no significant homology with any known toxins. Bioinformatic analysis showed that the enzyme has a degree of homology with known allergens, however, none were food allergens. No reports of sensitisation to any form of maltogenic alpha amylases were identified. Maltogenic alpha amylases from the same source organism are already permitted in the Code – one from a GM *Bacillus subtilis* containing the maltogenic α -amylase gene from *G. stearothermophilus*, and one by a GM strain of *Saccharomyces cerevisiae*, engineered to express an optimised variant of the maltogenic alpha amylase gene, also from *G. stearothermophilus*. On that basis, this enzyme is unlikely to pose an allergen risk to consumers when used as a processing aid in food.

The stated technological purpose of this enzyme is clearly articulated in the application. The evidence presented to support the proposed use of the enzyme provides adequate assurance that the enzyme is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme will be used at a level consistent with Good Manufacturing Practice (GMP), which limits the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect. The enzyme meets international purity specifications.

After undertaking its risk and technical assessment, FSANZ concludes that there are no public health and safety concerns with the use of maltogenic alpha amylase produced from a GM strain of *E. coli*, expressing a maltogenic alpha amylase gene from *G. stearothermophilus* under the proposed use conditions.

FSANZ has therefore prepared a draft variation to the Code, which if approved, would list the enzyme in the table to subsection S18—9(3) as a permitted processing aid for use in baking, brewing and starch processing, subject to the condition that the amount of enzyme used must be consistent with GMP.

FSANZ seeks submissions on the draft variation.

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 purpose of the application is to permit use of the enzyme maltogenic² alpha amylase (EC 3.2.1.133), sourced from a genetically modified (GM) strain of *Escherichia coli* (*E. coli* BLASC) as a processing aid in baking, brewing and starch processing.

Maltogenic alpha amylase hydrolyses 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 benefit of using this enzyme during baking, as claimed by the applicant, is the selective hydrolysis of starch that helps prevent retrogradation of starch in baked products, thus improving their shelf life. There are also 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 predominantly 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 where the enzyme performs its primary technological function during food processing.

The enzyme is produced by a GM strain of *E. coli*, expressing a maltogenic alpha amylase gene from *Geobacillus stearothermophilus* and would provide food processors with an alternative source of the enzyme preparation for use in the processing applications for which it has been developed.

Maltogenic alpha amylase is produced by submerged fed-batch pure culture fermentation, which involves the growth of the microorganism and production of the enzyme. Subsequent steps involve the separation of the enzyme from the microbial biomass, purification, concentration, spray-drying and formulation of the enzyme preparation.

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Australia New Zealand Food Standards Code (the Code). The requirements relevant to this application are summarised below.

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

² The term ‘maltogenic’ refers to the enzyme’s ability to break down starch into maltose.

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).

Identity and purity requirements

Subsection 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 (2006) and the United States Pharmacopeial Convention Food Chemicals Codex (12th edition, 2020).

Labelling requirements

Subsection 1.1.1—10(8) of the Code provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

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*³ (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 subsection 1.2.1—8(1) and

³ 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).

1.2.1—9(3), and section 1.2.1—15 respectively.

1.3.1 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 above.

1.4 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act; and
- it related to a matter that might be developed as a food regulatory measure.

1.5 Procedure for assessment

The application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

FSANZ has 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 maltogenic alpha amylase produced from a GM strain of *E. coli* 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. Bioinformatic analysis indicated that the enzyme shows no significant homology with any known toxins.

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 showed that the enzyme 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, this enzyme is unlikely to pose an allergen risk to consumers when used as a processing aid in food.

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.

The evidence presented to support the proposed use of the enzyme provided adequate assurance that the enzyme, in its recommended form and amounts, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The

enzyme meets international purity specifications.

For further details on the risk assessment, refer to SD1.

2.2 Risk management

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

- either reject the application;
- or to prepare a draft variation of the Code permitting the enzyme, maltogenic alpha amylase (EC 3.2.1.133) sourced from a GM strain of *E. coli*, to be used 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 Risk and Technical Assessment Report concluded that there are no safety concerns from using this enzyme for its stated purpose. In addition, the use of this enzyme, in the quantity and form proposed to be used, which must be consistent with GMP controls and processes, is technologically justified. Therefore, FSANZ has prepared a draft variation of the Code as outlined above (see Attachment A).

Other risk management considerations for this application are related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in Section 2.4.1.1 of this report take account of the safety of the enzyme.

2.2.1 Regulatory approval for enzymes

As stated above, FSANZ has prepared a draft variation to permit the use of the enzyme as a processing aid in baking, brewing and starch processing. 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)⁴.

2.2.2 Enzyme nomenclature

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB) uses the 'accepted' name 'glucan 1,4- α -maltohydrolase' for the enzyme with an EC number of EC 3.2.1.133. However, FSANZ has decided to use the name 'maltogenic α -amylase', which the IUBMB lists as one of the 'other' names for this enzyme, in the proposed draft variation to the Code, to remain consistent with how the already permitted maltogenic alpha amylases have been listed. 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.

2.2.3 Labelling requirements

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

2.2.3.1 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

⁴ 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 aids, subsection 1.5.2—4(2) states that the information relating to foods produced 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 maltogenic alpha amylase sourced from the 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, that 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 for labelling as ‘genetically modified’ would not apply to maltogenic alpha amylase 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)).

2.2.4 Risk management conclusion

The risk management conclusion is to permit maltogenic alpha amylase sourced from a GM strain of *E. coli*, expressing a maltogenic alpha amylase gene from *G. stearothermophilus*, as a processing aid (by amending the table to S18—9(3), which includes enzymes permitted for a specific technological purpose). The technological purpose is for use in baking, brewing and starch processing. The maximum permitted level is an amount consistent with GMP.

2.3 Risk communication

2.3.1 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 approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received from this call for submissions.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards (i.e. Codex Alimentarius Standards) and amending the Code to approve the enzyme as a processing aid is unlikely to have a significant effect on international trade.

Therefore, a notification to the WTO under Australia’s and New Zealand’s obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures

Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 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 permitting new processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting processing aids is machinery in nature and their use is voluntary. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given 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 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 (i.e. rejecting the application). This analysis considers permitting the use of maltogenic alpha amylase sourced from GM *E. coli* (the enzyme) as a processing aid for baking, brewing 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 measures. 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 use of the enzyme.

FSANZ's conclusions regarding costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at different conclusions.

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 is 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.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand and there is no relevant New Zealand only standard.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (see SD1) and concluded there were no public health and safety concerns associated with the proposed use of this enzyme.

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

The labelling considerations for the enzyme processing aid are discussed in Section 2.2.3 of this report.

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. 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 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 is there are 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*⁵ includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

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

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft 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.

⁵ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

4 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. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – 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 – Draft 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 maltogenic alpha amylase (EC 3.2.1.133) from a genetically modified (GM) strain of *Escherichia coli* (*E. coli*), 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 prepared a draft variation to the Code.

2. 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, maltogenic alpha amylase (EC 3.2.1.13) from a GM strain of *E. coli*, 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 has decided to use the alternative name ‘maltogenic α -amylase’ in the proposed draft variation to the Code, to remain consistent with how the already permitted maltogenic alpha amylases have been listed. A variation of this name i.e. ‘maltogenic **alpha** amylase’ has been used throughout the application and, as such, this document.

3. Documents incorporated by reference

The 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 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/WHO 2006) 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will occur for a seven-week consultation period.

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 permitting new processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting processing aids is machinery in nature and their use is voluntary. 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 would insert in the table to subsection S18—9(3) in Schedule 18 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.

If approved, the new entry would, in effect, permit the use of the enzyme, maltogenic alpha amylase (EC number 3.2.1.13), sourced from *E. coli* containing the maltogenic alpha amylase gene from *Geobacillus stearothermophilus*, as a processing aid for a specific technological purpose.

The permitted technological purpose for this enzyme would be use as a processing aid in baking, brewing and starch processing.

If approved, the permission would subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP.