18 June 2021
160-21

Approval report – Application A1210

Maltogenic alpha-amylase enzyme from GM *Saccharomyces cerevisiae*

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Lallemand Baking Solutions to permit a new source microorganism, being a genetically modified *Saccharomyces cerevisiae*, for the permitted enzyme, maltogenic alpha-amylase as a processing aid for use in the baking industry.

On 27 January 2021, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 9 June 2021. The Food Ministers' Meeting (formerly the Australia and New Zealand Ministerial Forum on Food Regulation) was notified of FSANZ's decision on 18 June 2021.

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

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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 (at Approval)

[1] https://www.foodstandards.gov.au/code/applications/Pages/A1210.aspx

Executive summary

The Australia New Zealand Food Standards Code (the Code) permits the enzyme maltogenic alpha-amylase (Enzyme Commission (EC) number 3.2.1.133) derived from a genetically modified (GM) strain of *Bacillus subtilis* to be used as a processing aid in the manufacture of all foods.

Lallemand Baking Solutions sought permission for maltogenic alpha-amylase derived from a different source to be used as a processing aid by submitting an application to Food Standards Australia New Zealand (FSANZ). Their enzyme is derived from a GM strain of *Saccharomyces cerevisiae*, engineered to express an optimised variant of the maltogenic alpha-amylase gene from *Geobacillus stearothermophilus*. This maltogenic alpha-amylase enzyme is protein engineered. The enzyme is proposed to be used as a processing aid in the manufacture of bakery products. The enzyme has improved thermostability compared to other comparable enzymes for use in the baking industry. The main use of the enzyme as a processing aid is to reduce crumb firmness and staling in bread, thereby improving the shelf life.

The evidence presented to support the proposed use of the enzyme provided adequate assurance that the enzyme, in the form and prescribed amounts, was technologically justified and had been demonstrated to be effective in achieving its stated purpose. The enzyme performed its technological purpose during production and manufacture of foods and was therefore appropriately categorised as a processing aid and not a food additive. The applicant provided evidence that this enzyme meets international purity specifications and had been authorised for use in the USA, and assessed as safe by the European Food Safety Authority.

FSANZ's safety assessment concluded that the use of the enzyme under the proposed conditions was safe. The host organism was neither pathogenic nor toxigenic and had a long history of safe use in food. The gene donor organism had a history of safe use for the production of food enzymes and raised no public health concerns. No issues were identified from the characterisation of the GM production strain. The enzyme showed no significant homology to any known toxins. A degree of homology between the protein engineered maltogenic alpha-amylase and several respiratory allergens was found. However, respiratory allergens are generally not food allergens, and since the enzyme was completely degraded under the conditions consistent with the human stomach, the risk of food allergy from the proposed uses of the enzyme was considered to be negligible.

Based on the reviewed toxicological data it was concluded that, in the absence of any identifiable hazard, an acceptable daily intake (ADI) 'not specified' was appropriate. A dietary exposure assessment was therefore not required.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 27 January 2021 and 10 March 2021.

FSANZ received two submissions from government agencies which both supported the draft variation.

For the reasons summarised in this report, FSANZ has decided to approve the draft variation proposed following assessment without change. The draft variation will amend subsection S18—9(3) of the Code to permit the use of the enzyme, maltogenic alpha-amylase, protein engineered variant, (EC number 3.2.1.133) from *Saccharomyces cerevisiae* containing the gene for maltogenic α-amylase from *Geobacillus stearothermophilus*, as a processing aid in the manufacture of bakery products. This permission will be subject to the condition that the

amount of enzyme used must be consistent with GMP.

Express permission for the enzyme to be used as a processing aid will also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology. This means that a food for retail sale or sold to a caterer that contains this maltogenic alpha-amylase as an ingredient (for example, 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.

1 Introduction

1.1 The applicant

Lallemand Baking Solutions is a division of Lallemand Inc. which specialises in providing yeasts, bacteria and their derivatives to businesses including food and alcoholic beverage businesses. Lallemand Baking Solutions specialise in the development and application of enzyme-based dough conditioners, yeast-based dough relaxers, and sour dough starters to the baking industry.

1.2 The application

The application sought to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme, maltogenic alpha-amylase (Enzyme Commission (EC) number 3.2.1.133), derived from a different source to be used as a processing aid. This enzyme is derived from a genetically modified (GM) strain of *Saccharomyces cerevisiae* (*S. cerevisiae*), engineered to express an optimised variant of the maltogenic alpha-amylase gene from *Geobacillus stearothermophilus* (*G. stearothermophilus*). The maltogenic alpha-amylase enzyme is protein engineered.

The enzyme is proposed to be used as a processing aid in the manufacture of bakery products. The enzyme is claimed by the applicant to have improved thermostability compared to other comparable enzymes for use in the baking industry. The main use of the enzyme as a processing aid was to reduce crumb firmness and staling in bread, thereby improving the shelf life.

1.3 The current Standard

Australian and New Zealand food laws require food for sale to comply with the following Code requirements.

1.3.1 Permitted use

Enzymes used in processing and manufacturing 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. 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 Good Manufacturing Practice (GMP).

Standard 1.3.3 and Schedule 18 list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3). An enzyme of microbial origin listed in the table to subsection S18—4(5) is permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. The table to subsection S18—9(3) lists those substances, including enzymes 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; and
- present in the food at a level not greater than the maximum permitted level specified in the table.

Maltogenic alpha-amylase from a different microorganism is permitted in the table to subsection S18—4(5); to be used in the manufacture of all foods. However, maltogenic alpha-amylase derived from *S. cerevisiae*, containing the gene for maltogenic alpha-amylase isolated from *G. stearothermophilus* is not currently permitted to be used as a processing aid.

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).

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.

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 20 (2017), in particular FAO/WHO 2006, for enzymes), and the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th edition). These include specifications for enzyme preparations used in food processing.

1.3.3 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 prevail.

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*[2] (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.

1.3.4 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). Standards set by Codex provide a benchmark against which national food measures and

[2] 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*).

regulations can be assessed. In certain situations however, FSANZ might receive an application to amend the Code for permission to use a new processing aid or food additive before an international standard exists.

There are also situations where domestic food standards will necessarily vary from international standards. This could include circumstances where:

- new data for the domestic situation that was not available at the time the international standard was set becomes available for assessment
- the domestic environment (climate and growing conditions) results in different levels of risk from contaminants, natural toxicants or nutrient levels in foods
- domestic consumption patterns result in different dietary exposures
- particular manufacturing and production processes have been adopted to meet specific domestic requirements.

Regulation (EC) No 1332/2008 (which became fully effective from January 2010) (the Regulation) harmonises for the first time the rules for food enzymes in the European Union (EU). Previous to the Regulation, food enzymes used as processing aids were not regulated at 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) and subsequently 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 (anticipated for release in 2020- 2021), EU countries' legislation applies.

The applicant's maltogenic alpha-amylase has been determined as Generally Recognized as Safe (GRAS) in the United States for the production of baked goods (GRAS notice GRN 842) via the GRAS process system, with a US Food and Drug Administration (FDA) no questions letter.

The applicant made application seeking approval for the enzyme in the European Union, and separately in Canada; both in April 2020.

The European Food Safety Authority Panel on Food Contact Materials, Enzymes and Processing Aids (EFSA CEP Panel) evaluated the enzyme that is the subject of this application. It concluded that the enzyme does not give rise to safety concerns under the intended conditions of use (EFSA 2021).

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

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 *Food Standards Australia New Zealand Act 1991* (the FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

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

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ sought public comments on the draft variation included in the call for submissions report between 27 January 2021 and 10 March 2021.

FSANZ received two submissions from government agencies which both supported the draft variation, and raised no issues that needed to be considered and addressed.

2.2 Risk assessment

The evidence presented to support the proposed use of the enzyme provides adequate assurance that the enzyme, in the quantity and form proposed to be used, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The applicant provided evidence that this enzyme meets international purity specifications. It has been authorised for use in the USA and considered safe for the intended purpose by EFSA.

The safety assessment concluded that the use of the enzyme under the proposed conditions is safe. The host organism is neither pathogenic nor toxigenic and has a long history of safe use in food. The gene donor organism has a history of safe use for the production of food enzymes and raises no public health concerns. The GM production strain was confirmed to contain the inserted DNA and this DNA was shown to be inherited across several generations. While there is a lack of history of safe use of this specific enzyme in food, the alpha-amylase extracted directly from the source organism has a long history of safe use. The enzyme shows no significant homology to any known toxins. A degree of homology between the protein engineered maltogenic alpha-amylase and several respiratory allergens was found. However, respiratory allergens are generally not food allergens, and since the enzyme is completely degraded under conditions with the human stomach, the risk of food allergy from the proposed uses of the enzyme is considered to be negligible.

Based on the reviewed toxicological data it is concluded that, in the absence of any identifiable hazard, an acceptable daily intake (ADI) ‘not specified’ is appropriate. A dietary exposure assessment was therefore not required.

2.3 Risk management

2.3.1 Regulatory approval for enzymes

FSANZ concluded that the enzyme of this application, maltogenic alpha-amylase meet its stated purpose as a processing aid in the manufacture of bakery products. The risk

assessment concluded that the enzyme itself, was unlikely to pose allergenicity or toxicity concerns and further concluded that in the absence of any identifiable hazard, an ADI of 'not specified' was appropriate for the enzyme.

Therefore, FSANZ prepared a draft variation permitting the use of the enzyme as a processing aid for its stated purpose.

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

2.3.2 Enzyme and source microorganism nomenclature

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 (IUBMB 1999). An alternate name listed is maltogenic alpha-amylase which is the name used by the applicant and that is listed in the table to subsection S18—4(5). This is therefore the name used in this report and in the approved draft variation to the Code.

The nomenclature of the production and gene donor microorganisms was checked and confirmed as being appropriate as listed in the application (see sections 3.1.1 and 3.1.2 of SD1). The production organism is *S. cerevisiae*, while *G. stearothermophilus* is the gene donor microorganism. These are both already listed as either production, source or donor microorganisms within Schedule 18.

2.3.3 Labelling requirements

The relevant labelling requirements related to the proposed permission are detailed below.

2.3.3.1 Labelling requirements for food produced using gene technology

Under current requirements in the Code, processing aids are, in most cases, exempt from the requirement to be declared in the statement of ingredients (see section 1.3.3). However paragraph 1.5.2—4(1)(b) of Standard 1.5.2 overrides this exemption when novel DNA or novel protein from the processing aid remains present in the final food. In such cases, the name of the processing aid must be declared on the label of the food in conjunction with the statement 'genetically modified'.

Novel DNA and novel protein is defined in subsection 1.5.2—4(5) to mean DNA or protein which, as a result of the use of gene technology, is different in chemical sequence or structure from DNA or protein present in counterpart food that has not been produced using gene technology, other than protein that:

(a) is *used as a processing aid or *used as a food additive[3]; and
(b) has an amino acid sequence that is found in nature.

The application states the enzyme expressed by the production strain was protein engineered, differing from the wild type maltogenic amylase sequence by three amino acids. Therefore, the enzyme protein was considered novel in relation to the definition.

[3] Both these terms are defined within Standard 1.1.2; being 1.1.2—13 and 1.1.2—11 respectively. The asterisk (*) indicates they are defined terms in the Code.

A food for retail sale or sold to a caterer that contains maltogenic alpha-amylase as an ingredient (for example, the enzyme is used in the manufacture of bread) will be required to be labelled 'genetically modified' in conjunction with the name of the enzyme (paragraph 1.5.2—4(1)(b)).

FSANZ notes however, if the bread made using the enzyme was not a food for sale itself (for example, 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 maltogenic alpha-amylase as 'genetically modified' will not apply because the labelling requirements only apply to food that consists of, or had as an ingredient, a GM food (section 1.5.2—4(1)).

2.3.4 Risk management conclusion

The risk management conclusion is to permit the enzyme, maltogenic alpha-amylase (EC 3.2.1.133), protein engineered derived from *S. cerevisiae*, containing the gene for maltogenic alpha-amylase isolated from *G. stearothermophilus* for use as a food processing aid. This enzyme 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 as a processing aid used in the manufacture of bakery products to improve the shelf life of bread. 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 also provides the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a basic 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 considers standard 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.

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

2.5 FSANZ Act assessment requirements

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 permitting new processing aids (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as the use of the new enzyme processing aid is voluntary once the application had been successfully approved. This standing exemption related to the introduction of a food to the food supply that had been determined to be safe.

FSANZ, however, had 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) of the FSANZ Act).

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 GM strain of *S. cerevisiae* as a processing aid into the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. FSANZ is of the view that no other realistic food regulatory measures exist.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered could not 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 derived from GM S. cerevisiae

Industry

Maltogenic alpha-amylase may help reduce crumb firmness and staling in bread, thereby improving the shelf life of bread. Due to the voluntary nature of the permission, industry will use the maltogenic alpha-amylase enzyme where they believe a net benefit exists. This enzyme is already available to industry from a different source. It may benefit industry to have this additional way of sourcing this enzyme, especially where it saves on costs.

Producing maltogenic alpha-amylase from GM *S. cerevisiae* is already permitted in the USA with permissions being sought in the European Union and Canada. The international permissions for enzyme from this particular source may be a business opportunity for Australian and New Zealand industries, although there may also be competing imports from these countries into the domestic market.

Consumers

Industry may pass some of the cost savings to consumers where it is cheaper to source maltogenic alpha-amylase enzyme from GM *S. cerevisiae*. Consumers may also benefit from a greater number of higher quality bread products if this additional source of maltogenic alpha-amylase leads to greater use of the enzyme.

Government

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

Conclusions from cost benefit considerations

FSANZ's assessment was that the direct and indirect benefits that would arise from permitting the use of the enzyme maltogenic alpha-amylase from GM *S. cerevisiae* for the proposed technological purposes would most likely outweigh the associated costs.

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 were considered below.

2.5.2 Subsection 18(1)

FSANZ had 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 had undertaken a safety assessment (SD1) and concluded there were no public health and safety concerns with permitting the use of maltogenic alpha-amylase sourced from a GM *S. cerevisiae,* as a processing aid in food for the proposed technological purposes.

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

The labelling requirements related to maltogenic alpha-amylase sourced from a GM *S. cerevisiae* are discussed in section 2.3.3 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 had used the best available scientific evidence to conduct the risk analysis, which 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 used in assessing the application.

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

There are no Codex Alimentarius Standards for enzymes. However, the US FDA did not respond with questions to a self-determination of this enzyme as GRAS in the US. EFSA also concluded that the enzyme does not give rise to safety concerns under the intended conditions of use. The applicant provided evidence that this enzyme also meets international specifications for enzyme preparations, being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes.

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

As mentioned above, the use of this enzyme is already permitted in the US. Therefore, the approval for use of this enzyme brings Australia and New Zealand into line with the US where it is already authorised for use. In this way, Australia and New Zealand will remain competitive with other international markets. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

- **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[4]**

The 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 use of maltogenic alpha-amylase sourced from a GM *S. cerevisiae* as a processing aid was consistent with the specific order principles for 'Technological Function'. All other requirements of the policy guidelines were similarly met.

3 References

EFSA CEP Panel (2021) Safety evaluation of the food enzyme maltogenic α-amylase from the genetically modified *Saccharomyces cerevisiae* strain LALL-MA. EFSA J 19(2):6434 https://doi.org/10.2903/j.efsa.2021.6434. Accessed 16 March 2021

FAO/WHO (2006) General specifications and considerations for enzyme preparations used in food processing. Accessed 9 December 2020

IUBMB (1999) IUBMB Enzyme Nomenclature EC 3.2.1.133 https://www.qmul.ac.uk/sbcs/iubmb/enzyme/EC3/2/1/133.html. Accessed 18 March 2021

[4] Formerly known as the Forum on Food Regulation.
[5] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals

The United States Pharmacopeia (2018) Food Chemicals Codex 11th Edition, United States Pharmacopeial Convention, Rockville, MD. Accessed 9 December 2020

Attachments

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

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

Food Standards (Application A1210 – Maltogenic alpha-amylase enzyme from GM *Saccharomyces cerevisiae*) Variation

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

Dated [To be completed by the Delegate]

[Insert name and title of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

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

1 Name

This instrument is the *Food Standards (Application A1210 – Maltogenic alpha-amylase enzyme from GM* Saccharomyces cerevisiae*) 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

[1] **Schedule 18** is varied by

[1.1] inserting into the table to subsection S18—9(3), in alphabetical order

Maltogenic α-amylase, protein engineered variant, (EC 3.2.1.133) sourced from *Saccharomyces cerevisiae* containing the gene for maltogenic α-amylase from *Geobacillus stearothermophilus*.	For use in the manufacture of bakery products	GMP

[1.2] inserting after the table to subsection S18—9(3)

Note Some enzyme sources identified in this table are protein engineered. If such an enzyme is used as a processing aid, the resulting food may have as an ingredient a food produced using gene technology, and the requirements relating to foods produced using gene technology will apply—see Standard 1.2.1 and Standard 1.5.2. The relevant enzymes are the following:

- Endo-1,4-ß-xylanase, protein engineered variant;
- Maltogenic α-amylase, protein engineered variant;
- Protein engineered enzymes used in the manufacture of various steviol glycosides.

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 A1210 which sought an amendment of the Code to permit the use of the enzyme, maltogenic alpha-amylase (EC 3.2.1.133) derived from a genetically modified (GM) strain of *Saccharomyces cerevisiae* (*S. cerevisiae*), containing the maltogenic alpha-amylase gene from *Geobacillus stearothermophilus*,(*G. stearothermophilus*) as a processing aid for use in manufacture of bakery products. This maltogenic alpha-amylase enzyme is described as being protein engineered. 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[6], 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 sunsetting 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 maltogenic alpha-amylase, protein engineered variant, (EC 3.2.1.133) derived from GM *S. cerevisiae* containing the maltogenic alpha-amylase gene from *G. stearothermophilus*, as a processing aid for use in the manufacture of bakery products.

3. Documents incorporated by reference

The variation in this instrument does not incorporate any documents by reference.

Existing provisions of the Code incorporate a document by reference that will prescribe identity and purity specifications for the processing aid permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2017) and the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th edition). These include specifications for enzyme preparations used in food processing.

[6] Formerly the Australia and New Zealand Ministerial Forum on Food Regulation. The Forum name change took effect on 21 February 2021 following a decision by Ministers.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1210 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 27 January 2021 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from needing to develop a Regulatory Impact Statement for proposed variations of the Code to permit additional processing aids (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting additional processing aids is likely to have only a minor impact on business and individuals. It is a minor, deregulatory change that allows for the introduction of a food product to the food supply that has been determined to be safe. The use of the approved processing aid is also voluntary.

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

Sub-item [1.1] of the Schedule to the variation inserts a new entry, in alphabetical order, into the table to subsection S18—9(3) in Schedule 18 of the Code.

The new entry permits the use as a processing aid of maltogenic alpha-amylase (EC 3.2.1.133) sourced from *Saccharomyces cerevisiae* containing the maltogenic alpha-amylase gene from *Geobacillus stearothermophilus*. The permission limits its use as a processing aid to the manufacture of bakery products. A condition of the permission is that the maximum permitted level or amount that may be used must be consistent with good manufacturing practice.

Sub-item [1.2] of the Schedule to the variation inserts a new note below the table to subsection S18—9(3). The purpose of the new note is to highlight that some enzymes listed in that table are protein engineered and that the requirements listed in Standard 1.2.1 and Standard 1.5.2 relating to foods produced using gene technology may apply to their use.