

27 July 2021
164-21

Call for submissions – Application A1211

Maltogenic alpha-amylase enzyme from GM *Bacillus licheniformis*

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Danisco New Zealand Ltd to permit a new source microorganism, being a genetically modified *Bacillus licheniformis*, for the permitted enzyme maltogenic alpha-amylase as a processing aid for use in brewing, manufacture of bakery products, the production of potable alcohol and starch processing. FSANZ 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) 8 September 2021

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:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

Table of contents

EXECUTIVE SUMMARY	4
1 INTRODUCTION.....	5
1.1 THE APPLICANT	5
1.2 THE APPLICATION	5
1.3 THE CURRENT STANDARD	5
1.3.1 <i>Permitted use</i>	5
1.3.2 <i>Identity and purity requirements</i>	6
1.3.3 <i>Labelling requirements</i>	6
1.3.4 <i>International standards</i>	6
1.4 REASONS FOR ACCEPTING APPLICATION	7
1.5 PROCEDURE FOR ASSESSMENT	7
2 SUMMARY OF THE ASSESSMENT	7
2.1 RISK ASSESSMENT	7
2.2 RISK MANAGEMENT	8
2.2.1 <i>Regulatory approval for enzymes</i>	8
2.2.2 <i>Enzyme and source microorganism nomenclature</i>	8
2.2.3 <i>Labelling requirements</i>	9
2.2.4 <i>Risk management conclusion</i>	9
2.3 RISK COMMUNICATION.....	10
2.3.1 <i>Consultation</i>	10
2.3.2 <i>World Trade Organization (WTO)</i>	10
2.4 FSANZ ACT ASSESSMENT REQUIREMENTS	10
2.4.1 <i>Section 29</i>	10
2.4.2 <i>Subsection 18(1)</i>	12
2.4.3 <i>Subsection 18(2) considerations</i>	12
3 DRAFT VARIATION	13
4 REFERENCES.....	13
ATTACHMENT A – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	15
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT.....	17

Supporting document

The following document¹ 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/A1211.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.

Danisco New Zealand Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) seeking permission for maltogenic alpha-amylase derived from a different source to be used as a processing aid. Their enzyme is derived from a GM strain of *Bacillus licheniformis*, engineered to express an optimised variant of the maltogenic alpha amylase gene from *Geobacillus stearothermophilus*. The enzyme is proposed as a processing aid for use in brewing, manufacture of bakery products, the production of potable alcohol and starch processing.

The evidence presented provides adequate assurance that the use of the enzyme, in the form and prescribed amounts proposed, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme performs its technological purpose during production and manufacture of foods and is therefore appropriately categorised as a processing aid and not a food additive. The enzyme meets international purity specifications and has been authorised for use in the USA, Denmark, Brazil and Singapore.

The safety assessment concluded that the use of the enzyme under the proposed conditions is safe. The host 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. No issues were identified from the characterisation of the GM production strain. The enzyme shows no significant homology to any known toxins. Some similarity was found between this enzyme and several non-food allergens. None of the identified allergens had an oral route of exposure and the *G. stearothermophilus* maltogenic alpha-amylases, already permitted in the Code, has a history of safe use in food. The risk of food allergy occurring from the proposed uses is considered unlikely.

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

If approved for use, this enzyme would be listed in the table to subsection S18—9(3), which includes enzymes permitted for a specific technological purpose.

The proposed 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.

1 Introduction

1.1 The applicant

Danisco New Zealand Ltd, a subsidiary of E. I. du Pont de Nemours and Company, is a manufacturer and marketer of speciality food ingredients, food additives and processing aids.

1.2 The application

The application seeks permission for a new microbial source for the currently permitted enzyme, maltogenic alpha amylase (Enzyme Commission (EC) number 3.2.1.133), as a processing aid in the Australia New Zealand Food Standards Code (the Code). The enzyme is derived from a genetically modified (GM) strain of *Bacillus licheniformis* (*B. licheniformis*) containing the maltogenic alpha amylase gene from *Geobacillus stearothermophilus* (*G. stearothermophilus*).

The enzyme is proposed as a processing aid for use in brewing, manufacture of bakery products, the production of potable alcohol and starch processing.

1.3 The current standard

Australian and New Zealand food laws require that food for sale 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.

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).

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 *B. subtilis*, containing the gene for maltogenic alpha amylase isolated from *G. stearothermophilus*, is not currently permitted to be used as a processing aid. Food Standards Australia New Zealand (FSANZ) is currently assessing another application ([A1210](#)) seeking permission for maltogenic alpha amylase derived from *Saccharomyces cerevisiae*, containing the gene for maltogenic alpha amylase isolated from *G. stearothermophilus* (FSANZ, 2021).

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.

Subsection 1.2.3—4(1) requires certain food 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 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 food* (GM food)². The requirements imposed by section 1.5.2—4 generally apply 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

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*).

relevant international standard setting body is the Codex Alimentarius Commission (Codex). Standards set by Codex provide a benchmark against which national food measures and 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 (the Regulation) harmonises the rules for food enzymes in the European Union (EU). Previous to the Regulation taking effect in 2010, 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 self-determined as Generally Recognized as Safe (GRAS) in the USA via the US Food and Drug Administration (FDA) GRAS process system. It was considered GRAS for use in starch processing, baking, potable alcohol production and brewing. It is also approved in Denmark, Singapore and Brazil.

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* (FSANZ Act) as it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

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

2 Summary of the assessment

2.1 Risk assessment

FSANZ has assessed the public health and safety risks associated with maltogenic alpha-amylase sourced from *Bacillus licheniformis* containing the maltogenic alpha-amylase gene

from *Geobacillus stearothermophilus* as a processing aid (see SD1). The summary of this risk assessment is provided below.

While permission for maltogenic alpha-amylase already exists in the Code, this applicant is seeking permission for a new source, with a new specification.

The enzyme is manufactured by fermentation, using a genetically modified bacterium. A **microbiological assessment** concluded that the host strain has a recognised safe history of use. It is also neither pathogenic nor toxigenic. A **biotechnology assessment** found the production strain is safe.

A **food technology assessment** confirmed the enzyme achieves its stated purpose at the amount and form specified. The enzyme meets international purity specifications and has been authorised for use in the USA, Denmark, Brazil and Singapore.

A **toxicological assessment** combined with a **dietary exposure assessment** concluded the use of the enzyme under the proposed amounts and conditions is safe. In the absence of any identifiable hazard, an acceptable daily intake (ADI) 'not specified' is appropriate. The **toxicological assessment** also found no similarity between the enzyme and known toxins. While there is some similarity to non-food allergens, evidence such as the source of the enzyme already existing in the Code shows this enzyme has a history of safe use in food.

In summary, FSANZ concludes there are no safety concerns associated with the use of maltogenic alpha-amylase produced by microbial fermentation as a processing aid.

2.2 Risk management

2.2.1 Regulatory approval for enzymes

FSANZ has concluded that maltogenic alpha-amylase from a GM strain of *Bacillus licheniformis* meets its stated purpose as a processing aid in baking, brewing, potable alcohol production and starch processing. The risk assessment concluded that the enzyme is unlikely to pose allergenicity or toxicity concerns and further concluded that in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme.

Therefore, FSANZ prepared a draft variation to permit 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 will 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).

2.2.2 Enzyme and source microorganism nomenclature

FSANZ noted 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 that is used in this report and in the proposed drafting variation to the Code.

The nomenclature of the production and gene donor microorganisms as listed in the application was confirmed as being appropriate (see sections 3.1.1 and 3.1.2 of SD1). The production organism is *B. licheniformis*, while *G. stearothermophilus* is the gene donor

microorganism. These are both already listed as either production, source or donor microorganisms within Schedule 18.

2.2.3 Labelling requirements

The generic exemption from listing processing aids in the statement of ingredients would apply to foods produced using this processing aid (see section 1.3.3 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 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 strain *B. subtilis* as an ingredient (e.g. bread) would be required to be labelled ‘genetically modified’ in conjunction with the name of the enzyme.

2.2.3.2 Declaration of certain substances

Section 3.3.5 of SD1 states the enzyme preparation contains wheat starch and wheat flour. If wheat and gluten from wheat are present in a food for sale³, including when present as a processing aid or an ingredient or component of a processing aid, they must be declared unless an exemption applies (Division 3 of Standard 1.2.3). If the food is not required to bear a label, the information must be displayed in connection with the display of the food or provided to the purchaser on request (subsections 1.2.1—9(6) and (7) of Standard 1.2.1).

Soy products were used as ingredients in the fermentation medium for the enzyme preparation, although the applicant states soy is undetectable in the final enzyme preparation (section 3.3.5 of SD1). If however soy is present in the food for sale, it must be declared. Existing exemptions from the requirement to declare soy (refer to subsection 1.2.3—4(4)) do not apply to the products intended to be manufactured using this enzyme.

2.2.4 Risk management conclusion

The risk management conclusion is to permit the enzyme maltogenic alpha-amylase (EC 3.2.1.133) derived from *B. licheniformis*, containing the gene for maltogenic alpha amylase isolated from *G. stearothermophilus* for use as a food processing aid. If approved, the permission will be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The technological purpose of this enzyme is as a processing aid for use in brewing, manufacture of bakery products, the production of potable alcohol and starch processing. The maximum level at which the enzyme may be present in the food is an amount consistent with GMP. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code will also provide the permission for the enzyme’s potential presence in the food for sale as a food produced using gene technology. Unless exempt, mandatory declarations for wheat, gluten

³ On 25 February 2021 the Code was amended to introduce new requirements for the labelling of allergens in food, including a requirement to declare gluten when it is present in a food for sale. Suppliers have until 25 February 2024 to change over to these new requirements. If a food was packaged and labelled before 25 February 2024 and it complied with the previous allergen labelling requirements, then that food can remain on sale for another two years as long as it complies with the rest of the Code.

and soy will apply when present in a food for sale to inform individuals that are allergic to wheat and soy, or intolerant to gluten.

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 considers 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 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 and amending the Code to permit a new microbial source of a currently permitted enzyme is unlikely to have a significant effect on international trade as Codex does not have regulations for enzymes used as processing aids. 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 permitting new processing aids (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as the use of a new enzyme processing aid is voluntary once the application has been successfully approved. 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) of the FSANZ Act).

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 derived from a GM strain of *B. licheniformis* 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, however information received during public consultation may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, 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.

Costs and benefits of permitting the use of enzyme maltogenic alpha-amylase derived from GM B. licheniformis

Industry

Maltogenic alpha-amylase may provide benefits in baking, brewing, potable alcohol production and starch processing. Due to the voluntary nature of the permission, industry will use the maltogenic alpha-amylase enzyme where they believe a net benefit exists for them. 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.

Maltogenic alpha-amylase from GM *B. licheniformis* is already permitted in the USA, Denmark, Brazil and Singapore. The international permissions for an additional source of this enzyme 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 *B. licheniformis*. Consumers may also benefit from a greater number of higher quality food products if this additional source of maltogenic alpha-amylase leads to greater use of the enzyme.

Government

Permitting this additional source of maltogenic alpha-amylase may result in a small cost to government in terms of adding the permitted source 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 enzyme maltogenic alpha-amylase from GM *B. licheniformis* for the proposed technological purposes 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

Schedule 18 of the Code applies in both Australia and New Zealand. There are no other relevant New Zealand only standards.

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

2.4.2.2 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 *B. licheniformis* are discussed in section 2.2.3 above.

2.4.2.3 The prevention of misleading or deceptive conduct

There are 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 has 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 enzyme has been self-determined as GRAS in the USA and so permitted for the proposed purpose. It is also permitted in Denmark, Brazil and Singapore. It 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 USA, Denmark, Brazil and Singapore. Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with the other countries 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 Forum on Food Regulation⁴**

The Ministerial Policy Guideline Addition to Food of Substances other than Vitamins and Minerals⁵ includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

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

FSANZ has determined that permitting the use of maltogenic alpha-amylase sourced from a GM *B. subtilis* as a processing aid is consistent with the specific order principles for 'Technological Function'. All other requirements of the policy guidelines 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.

4 References

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

FSANZ (2021) Application A1210 – Maltogenic alpha-amylase enzyme from GM *Saccharomyces cerevisiae*, <https://www.foodstandards.gov.au/code/applications/Pages/A1210.aspx>. Food Standards Australia New Zealand, Canberra

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

US FDA (2018). GRAS No. 751 (Maltogenic alpha-amylase from *Bacillus stearothermophilis* produced in *Bacillus subtilis*) and the FDA response letter. Available at https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=751&sort=GRN_No&order=DESC&startrow=1&type=column&search=Substance%C2%A4VARCHAR%C2%A4maltogenic%20alpha%2Damilase

⁴ From 21 February 2021 it is now called the 'Food Ministers' Meeting', following a decision by Ministers.

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. 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 A1211 – Maltogenic alpha-amylase enzyme from GM *Bacillus licheniformis*) Variation

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

Dated [To be completed by the Delegate]

[Insert 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 A1211 – Maltogenic alpha-amylase enzyme from GM Bacillus licheniformis) 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 inserting into the table to subsection S18—9(3), in alphabetical order

Maltogenic α -amylase (EC 3.2.1.133) sourced from *Bacillus licheniformis* containing the gene for maltogenic α -amylase from *Geobacillus stearothermophilus*.

For use in:

- (a) brewing;
- (b) the manufacture of bakery products;
- (c) the production of potable alcohol;
and;
- (d) starch processing.

GMP

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 A1211 which seeks to permit a new source microorganism, being a genetically modified *Bacillus licheniformis*, for the permitted enzyme, maltogenic alpha-amylase. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The Authority has prepared a draft variation amending the table to section S18—9(3) of the Code to permit the use of maltogenic alpha-amylase (EC 3.2.1.133) sourced from *Bacillus licheniformis* containing the maltogenic alpha-amylase gene from *Geobacillus stearothermophilus* as a processing aid for use in brewing, manufacture of bakery products, the production of potable alcohol and starch processing.

3. Documents incorporated by reference

The variations to food regulatory measures do 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 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) 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.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1211 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 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

Item [1] of the Schedule to the variation will insert a new entry into the table to subsection S18—9(3) in Schedule 18 of the Code.

The new entry would permit the use as a processing aid of maltogenic alpha-amylase (EC 3.2.1.133) sourced from *Bacillus licheniformis* containing the maltogenic alpha-amylase gene from *Geobacillus stearothermophilus*. The permission would limit its use as a processing aid in brewing, the manufacture of bakery products, the production of potable alcohol, and starch processing. A condition of the permission is that the maximum permitted level or amount that may be used must be consistent with good manufacturing practice.