



27 October 2020
[139-20]

Call for submissions – Application A1204

Beta-amylase from soybean (*Glycine max*) as a processing aid (enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an Application made by Danisco New Zealand to permit beta-amylase from soybean (*Glycine max*) as a processing aid (enzyme) in starch processing for the production of maltose syrup. 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 1991*. 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 December 2020

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.

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Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION.....	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION.....	3
1.3 THE CURRENT STANDARD	3
1.3.1 <i>International standards</i>	4
1.4 REASONS FOR ACCEPTING APPLICATION	5
1.5 PROCEDURE FOR ASSESSMENT	5
2 SUMMARY OF THE ASSESSMENT.....	5
2.1 RISK ASSESSMENT	5
2.2 RISK MANAGEMENT	6
2.2.1 <i>Regulatory approval for enzymes</i>	6
2.2.2 <i>Enzyme nomenclature</i>	6
2.2.3 <i>Labelling requirements</i>	6
2.2.4 <i>Risk management conclusion</i>	7
2.3 RISK COMMUNICATION.....	7
2.3.1 <i>Consultation</i>	7
2.3.2 <i>World Trade Organization (WTO)</i>	7
2.4 FSANZ ACT ASSESSMENT REQUIREMENTS	7
2.4.1 <i>Section 29</i>	8
2.4.2 <i>Subsection 18(1)</i>	9
2.4.3 <i>Subsection 18(2) considerations</i>	9
3 DRAFT VARIATION	10
4 REFERENCES.....	11
ATTACHMENT A – DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	12
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT.....	14

Supporting document

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

SD1 Risk and technical assessment report

Executive summary

Danisco New Zealand Ltd (Danisco) submitted an application to Food Standards Australia New Zealand (FSANZ) to permit a new source of the already permitted enzyme beta-amylase (β – amylase) (EC 3.2.1.2) for use as a processing aid in starch processing for the production of maltose syrup. This β -amylase is produced from conventional (i.e. not genetically modified) soybeans (*Glycine max*).

Enzymes used to produce and manufacture food are considered processing aids and are regulated by the *Australia New Zealand Food Standards Code* (the Code). If approved for use, this enzyme would be listed in the table to subsection S18—9(3) of the Code, which lists substances (including enzymes) permitted for use as processing aids for specific technological purposes.

After undertaking a risk assessment, FSANZ concluded that there are no safety concerns associated with using this new source of β -amylase. β -Amylase from soybean is derived from the edible parts of the *Glycine max* plant, for which a history of safe use over generations is well known. In the absence of any identifiable hazard, an acceptable daily intake (ADI) of 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The evidence presented to support the proposed use of the enzyme provides adequate assurance that the enzyme, in the form and prescribed amounts, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme meets international identity and purity specifications.

FSANZ has prepared a draft variation to the Code to permit β -amylase produced from soybean as a processing aid for use in starch processing to manufacture maltose syrup. This is subject to the condition that the amount of enzyme used must be consistent with good manufacturing practice (GMP). FSANZ seeks submissions on the draft variation.

1 Introduction

1.1 The Applicant

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

1.2 The Application

FSANZ received an application seeking permission for an already permitted enzyme, beta-amylase (β -amylase) (EC 3.2.1.2) as a processing aid, from a new source. The new source of the enzyme is conventional (i.e. not genetically modified) soybeans (*Glycine max*).

If approved, this β -amylase will be used as a processing aid in starch processing to produce maltose syrup. β -Amylase will be used as a processing aid at low levels and is either not present in the final food or present in insignificant quantities, having no technical function in the final food.

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with the following requirements of the *Australia New Zealand Food Standards Code* (the Code).

Permitted use

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

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a processing aid' unless that substance's use as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance 'used as a processing aid' in relation to a food is a substance used during the course of processing that meets all of the following conditions: it is used to perform a technological purpose during the course of processing; it does not perform a technological purpose in the food for sale; and it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at good manufacturing practice (GMP).

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

There are currently permissions for β -amylase (EC 3.2.1.2) from both plant origin and microbial origin within the tables to subsection S18—4(4) and subsection S18—4(5)

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respectively, to be used in the manufacture of all foods. However, β -amylase from this particular plant source (soybean) is not currently permitted.

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)) and the United States Pharmacopeial Convention Food chemicals codex (United States Pharmacopeial Convention 11th edition (2018)). Certain earlier publications from these primary sources include the relevant specifications for enzyme preparations used in food processing (JECFA (2006) and FCC (2008), respectively).

Labelling requirements

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

Subsection 1.2.3—4(1) requires certain foods and substances to be declared when present in a food for sale. Paragraph 1.2.3—4(2)(c) states the food or substance may be present as a substance or food used as a processing aid, or an ingredient or component of such a substance or 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.

1.3.1 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 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.

In contrast to food additives, there is no Codex Alimentarius 'general standard' for enzymes.

Regulation (EC) No 1332/2008 (the Regulation) harmonises the rules for food enzymes in the European Union (EU). Previous to the Regulation, food enzymes used as processing aids were not regulated at 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 Member States' legislation applies.

β -amylase from soybean has been evaluated by the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (EFSA 2017). The Panel did not identify any safety issues with β -amylase produced from soybean.

β -Amylase is permitted for use in China (China 2015) and Japan (Japan 1996).

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
- 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.

2 Summary of the assessment

2.1 Risk assessment

FSANZ has assessed the public health and safety risks associated with β -amylase produced from soybean (*Glycine max*) used as a processing aid in starch processing to produce maltose syrup (see SD1). The summary of this risk assessment is provided below.

The food technology assessment concluded that β -amylase is technologically justified and effective in achieving its stated purpose. It performs its technological purpose during production of maltose syrup, and is therefore appropriately categorised as a processing aid. β -Amylase needs to meet the identify and purity specifications set out in the Code to be sold in Australia and New Zealand.

β -Amylase from soybean is derived from the edible parts of the *Glycine max* plant, for which a history of safe use over generations is well known. The enzyme also meets international identity and purity specifications.

FSANZ considers that soybean β -amylase is unlikely to pose an allergenicity concern. Bioinformatic analysis identified a degree of amino acid sequence homology between β -amylase from soybean and an allergenic protein from wheat, but FSANZ does not consider β -amylase to be of allergenic concern in wheat allergic individuals given the likely very low exposure and that the enzyme is likely to be digested in the stomach like other dietary proteins.

The WHO/IUIS Allergen Nomenclature Database lists seven soy proteins that are food allergens. β -Amylase from soybean is not one of these seven allergenic soy proteins and is not an allergen to individuals with soybean food allergy. However, as the enzyme is derived from soy it is possible that the enzyme preparation may contain traces of these allergenic proteins due to carry over from the production process. Risk management measures that would apply if soy is present in the enzyme preparation are discussed in Section 2.2.3.1.

Based on the available evidence there are no safety concerns from the proposed uses of β -

amylase from soy as a processing aid. Given the long history of safe use of soy and soy products and the absence of an identifiable hazard from the enzyme, an acceptable daily intake (ADI) 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

2.2 Risk management

The risk assessment concluded that there are no safety concerns relating to Danisco's β -amylase as a food processing aid in the manufacture of maltose syrup. As processing aids require permissions in the Code, the main risk management option available to FSANZ is to approve or reject the request to amend the Code and, if approved, to impose any conditions that may be appropriate. Other risk management issues 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.

If permitted, this enzyme preparation will provide the food industry with an alternative source of β -amylase.

2.2.1 Regulatory approval for enzymes

FSANZ has concluded in its food technology assessment that Danisco's β -amylase meets its stated purpose as a processing aid in the production of maltose syrup.

From its risk assessment, FSANZ has further concluded that in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme. The risk assessment also concluded that the enzyme itself is unlikely to pose an allergenicity or toxicity concern, aside from the possible presence of soy protein, a known allergen.

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

2.2.2 Enzyme nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name ' β -amylase' for the enzyme with an EC number of EC 3.2.1.2 (IUBMB 2020). This is the name that is used in the draft variation to the Code.

β -Amylase (EC 3.2.1.2) is already listed in the tables to subsections S18—4(4) and S18—4(5) of the Code and, if approved, will be listed in the table to subsection in S18—9(3).¹

2.2.3 Labelling requirements

In preparing a draft variation to permit the use of the enzyme as a processing aid, the generic exemption from listing processing aids in the statement of ingredients will apply to foods containing this processing aid.

2.2.3.1 Declaration of certain substances

As the enzyme is derived from soy, the risk assessment (section 3.3 of SD1 to this report) concluded that it may contain traces of allergenic soybean proteins. When soy is present, including when present as a processing aid or an ingredient or component of a processing aid, it must be declared in accordance with section 1.2.3—4 of Standard 1.2.3 (Information

¹ The term that will be used in the proposed draft variation to the Code for this enzyme is β -Amylase EC 3.2.1.2, as this will ensure consistency with other existing permissions in Schedule 18 of the Code.

requirements – warning statements, advisory statements and declarations). There are requirements in Standard 1.2.1 (Requirements to have labels or otherwise provide information) as to how and where such declarations must be made. For example, if the food is food for retail sale and is not required to bear a label, the declaration must be displayed in connection with the display of the food or provided to the purchaser on request (see paragraph 1.2.1—9(7)(b)).

Certain products are exempt from the requirement to declare soy e.g. soybean derivatives that are a tocopherol or a phytosterol (sub-subparagraph 1.2.3—4(1)(b)(vii)(B)). However these exemptions do not apply to whey from soybean, which is the ingredient used during the production of this enzyme.

2.2.4 Risk management conclusion

The risk management conclusion is to permit the enzyme, β -amylase (EC 3.2.1.2) sourced from soybean (*Glycine max*). 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 use as a processing aid in starch processing to produce maltose syrup. The maximum level at which the enzyme may be present in the food is an amount consistent with GMP. Labelling requirements will apply if soy is present in a food for sale to inform soy-allergic individuals.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a basic 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 not any relevant international standards and amending the Code to permit a new plant source of a currently permitted enzyme is unlikely to have a significant effect on international trade as Codex does not have a general standard 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 the new enzyme process 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)).

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. where the status quo is rejecting the application). This analysis considers permitting an already permitted enzyme, β -amylase (EC 3.2.1.2) from a new source, as a processing aid. The enzyme is derived from soybean (*Glycine max*).

If approved, this β -amylase will be used as a processing aid in starch processing to produce maltose syrup. β -amylase will be used as a processing aid at low levels and is either not present in the final food or present in insignificant quantities, having no technical function in the final food.

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 the use of the enzyme.

Costs and benefits of permitting for a new source of the already permitted enzyme (β -amylase) for use as a processing aid in the production of maltose syrup from starch

Enzyme preparations are widely used as processing aids in the manufacture of food products. Currently no β -amylase from soybean is permitted as a processing aid. Approval of this application would provide food processors with a new enzyme preparation.

Due to the voluntary nature of the permission, manufacturers would only use β -amylase from soybean (*Glycine max*) as a processing aid (enzyme) in the production of maltose syrup by starch processing, where they believe a net benefit exists for them. Part of any cost savings to industry may be passed onto consumers.

This β -amylase preparation is permitted for use in China and Japan. The international permissions for 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.

Permitting the enzyme may result in a small cost to government in terms of adding the enzyme 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 β -amylase from soybean (*Glycine max*) as a processing aid (enzyme) in the production of maltose syrup by starch processing, 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 β -amylase sourced from soybean (*Glycine max*), 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 β -amylase sourced from soybean (*Glycine max*) are discussed in Section 2.2.3 of this report above. The requirement for the declaration of certain foods and substances when present applies to enable consumers to make informed choices.

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 assessment, 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 considered by FSANZ in assessing the application.

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

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There is no Codex Alimentarius general standard for enzymes (in contrast to the Codex General Standard for Food Additives). However, Danisco's β -amylase meets international specifications for enzyme preparations, being the JECFA Compendium of Food Additive Specifications (JECFA 2006) and the Food Chemicals Codex (FCC 2008) specifications for enzymes (refer to Section 1.3 of this report).

The enzyme is permitted in China and Japan, and an EFSA safety assessment (EFSA 2017) did not identify any safety concerns.

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

As mentioned above, approval for use of this enzyme would bring Australia and New Zealand into line with other jurisdictions where it is already authorised for use (China and Japan), and is consistent with the outcome of the safety assessment by EFSA. 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 conclusion of the risk assessment was there are no public health and safety issues associated with β -amylase from soybean a food processing aid in the manufacture of maltose syrup by starch processing. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme as an alternative to those currently permitted. Which enzyme preparation a food manufacturing company uses will depend on a number of economic and other factors.

- **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 Minerals² 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 β -amylase sourced from soybean 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

² [Food regulation website](#)

accompany an instrument if it is lodged on the Federal Register of Legislation.

4 References

China (2015). [China GB2760-2015 standard](#) Accessed 14 September 2020.

EC (2008). [Regulation \(EC\) No 1332/2008](#) of 16 December 2008 on food enzymes. Accessed 14 September 2020.

EFSA (2017). EFSA Panel on Food Contact Materials, Enzymes and Processing Aids. [Safety evaluation of the food enzyme beta-amylase obtained from soybean \(*Glycine max*\)](#)
EFSA Journal 2017;15(5): e04757. Accessed 7 September 2020.

FCC (2008). Enzyme preparations. In: Food Chemicals Codex, 6th edition. Rockville (MD): United States Pharmacopeial Convention, pp. 413-417.

[IUBMB \(2020\) EC 3.2.1.2](#) (website last updated August 2020).

Japan (1996). [Japan Specifications and Standards for Food Additives 9th edition](#). Accessed 14 September 2020.

JECFA (2006). General specifications and considerations for enzyme preparations used in food processing [prepared by the Committee at its sixty-seventh meeting (2006)]. In: *Combined Compendium of Food Additive Specifications [Online Edition]. General Specifications for Enzymes Analytical Methods, Volume 4: Analytical Methods, Test Procedures and Laboratory Solutions Used by and Referenced in the Food Specifications*. 1st to 67th JECFA Meetings, 1956-2006. (FAO JECFA Monographs 1). Rome, Italy: Food and Agriculture Organization of the United Nations (FAO) / Geneva, Switz.: Joint FAO/WHO Expert Committee on Food Additives (JECFA), xviii - xxv. Available at: <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>. Accessed 10 September 2020.

The United States Pharmacopeia (2018). [Food Chemicals Codex 11th Edition](#), United States Pharmacopeial Convention, Rockville, MD. Accessed 14 September 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 A1204 – Beta-amylase from soybean (*Glycine max*) as a processing aid (enzyme)) 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.

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1 Name

This instrument is the *Food Standards (Application A1204 – Beta-amylase from soybean (Glycine max) as a processing aid (enzyme)) 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

β-Amylase (EC 3.2.1.2) sourced from soybean (*Glycine max*)

For use in starch processing to manufacture maltose syrup

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 A1204 which seeks to permit the use of the enzyme, beta-amylase (β -Amylase) from soybean (*Glycine max*) as a processing aid for use in starch processing to produce maltose syrup. 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 the enzyme, β -Amylase (EC 3.2.1.2) sourced from soybean (*Glycine max*), as a processing aid in starch processing to produce maltose syrup.

3. Documents incorporated by reference

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

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A11204 will include one round of public consultation following an assessment and the preparation of a draft Standard 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 new processing aids (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting new 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] inserts a new entry, in alphabetical order, into the table to subsection S18—9(3) of the Code.

The new entry consists of the enzyme, β -Amylase (EC 3.2.1.2) sourced from soybean (*Glycine max*), as a processing aid in food for a specific technological purpose.

The technological purpose is for use in starch processing to manufacture maltose syrup.

The permission is 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 good manufacturing practice.