26 March 2021
152-21

Approval report – 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 manufacture of maltose syrup.

On 27 October 2020, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions, plus one late submission.

FSANZ approved the draft variation on 17 March 2021. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 26 March 2021.

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

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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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 manufacture 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). The draft variation will amend Schedule 18, specifically by listing this enzyme 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.

FSANZ carried out a risk assessment and 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-established.

In the absence of any identifiable hazard, an acceptable daily intake (ADI) of 'not specified' has been assessed as being appropriate. A dietary exposure assessment was therefore not required.

The evidence presented to support the proposed use of the enzyme as a processing aid provided adequate assurance that the enzyme is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme meets international identity and purity specifications.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 27 October 2020. Three submissions were received, all of which FSANZ has had regard to (see Section 2.1 of this report for details of submissions made). In addition, one late submission was received which opposed the application, however no reasons were provided for the opposition.

FSANZ has decided to approve the draft variation proposed following assessment without change. The draft variation amends the Code to permit β-amylase (EC 3.2.1.2) sourced from soybean (*Glycine max*) 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).

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

The application sought 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*).

The technological purpose of this β-amylase is use as a processing aid in starch processing to manufacture 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 technological 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)

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(5)(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, Food Standards Australia New Zealand (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 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 from soybean (*Glycine max*) is permitted for use in China (China 2015).

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)
- 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 after FSANZ had regard to all submissions that FSANZ received following the call for submissions. The approved draft variation is at Attachment A. The approved draft variation takes effect on gazettal.

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 assessment

2.1 Summary of issues raised in submissions

FSANZ sought submissions on the draft variation from 27 October to 8 December 2020.[2] Three submissions were received within the submission period, one from Allergy & Anaphylaxis Australia, one from a government agency, and one from an industry body. All submissions supported the application however Allergy & Anaphylaxis Australia made comments regarding labelling, allergenicity, processing and digestion. The issues raised by Allergy & Anaphylaxis Australia have been addressed and are noted in Table 1 below. Supportive comments by two submitters are also noted in the table. In addition, one late submission was received opposing the application, however no reasons were provided for the opposition.

Table 1: Summary of submissions

Issue or comment	Raised by	FSANZ response
Labelling – notes that labelling will be required if soy is present in the	Allergy & Anaphylaxis Australia	Noted.

[2] These submissions are on the FSANZ website at: A1204 - Beta-amylase from soybean (Glycine max) as a processing aid

Issue or comment	Raised by	FSANZ response
food for sale, and that FSANZ should state the labelling obligation more emphatically.		Section 2.2.4 of the Call for Submissions report; and Sections 2.3.3 and 2.3.4 of this report, state that existing labelling requirements will apply if soy is present in a food for sale to inform soy-allergic individuals. This includes a requirement to declare the presence of certain food (including substances) in a food for sale. See sections 1.3 of the Call for Submissions and this report.
Allergenicity – questions the evidence for the statement: "Soybean β-amylase is not an allergen to individuals with soy bean food allergy".	Allergy & Anaphylaxis Australia	Section 2.1 of the Call for Submissions and Section 2.2 of this report explains that not all proteins in soy are allergenic. The WHO/IUIS[3] Allergen Nomenclature database lists seven proteins in soybeans that are food allergens. Soybean β-amylase is not included in this list, and no reports of food allergy responses to β-amylase from soybean have been identified. Refer to section 3.3 of SD1. Section 2.1 of the Call for Submission report discusses that as the enzyme is derived from soy, it is possible that the *enzyme preparation*[4] may contain traces of the seven soybean proteins considered to be food allergens (due to carry over from the production process). In circumstances where soy is present in a food for sale arising from the use of β-amylase from soybean as a processing aid, existing labelling requirements in the Code will apply to inform soy-allergic individuals about the food.
Processing and digestion – stated that proteins that are denatured can still be allergenic by making a new epitope not exposed in the original food. Likelihood of digestion in the stomach should not allay any concerns of allergenicity.	Allergy & Anaphylaxis Australia	FSANZ's allergenicity assessment of the enzyme was based on the overall weight of evidence, not solely on evidence of denaturation or digestion. This is consistent with recent FAO/WHO guidance on assessment of food enzymes which notes that data on resistance to pepsinolysis may have some utility as part of a weight of evidence

[3] International Union of Immunological Societies

[4] Refer to the JECFA 2006 specification for enzyme preparations that explains that enzymes are used in food processing as enzyme preparations; that an enzyme preparation contains the active enzyme and intentionally added formulation ingredients, and may contain constituents of the source organism (i.e. an animal, plant, or microbial material from which an enzyme was isolated).

Issue or comment	Raised by	FSANZ response
		approach. Soybean β-amylase itself is not considered a soybean food allergen. The enzyme shared a degree of sequence homology with an allergenic protein from wheat, but clinically significant cross-reactivity between soybean allergy and wheat allergy has not been reported (Cox et al. 2021; EFSA 2014). Individuals with wheat allergy are not generally advised to avoid soy, and vice versa. A study of the risk of food allergy among soy-allergic consumers consuming wheat contaminated with low levels of soy noted a lack of evidence of allergic reactions among soy-allergic consumers to wheat-based products (Remington et al. 2013). This information, taken together with the expected low levels of exposure and evidence of digestibility supports the conclusion that soybean β-amylase itself is not expected to be of allergenicity concern. This conclusion is consistent with EFSA's safety evaluation of soybean β-amylase (EFSA 2017).
Supports the draft variation proposed. Notes that labelling requirements will apply if soy is present in the food for sale.	New Zealand Food Safety (Ministry for Primary Industries)	Noted.
Supports the draft variation proposed. Notes that the product will provide manufacturers with another alternative source of beta-amylase.	New Zealand Food and Grocery Council	Noted.
Does not support. No reason was provided.	Late comment – private submitter.	Noted.

2.2 Risk assessment

FSANZ 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 manufacture maltose syrup (see SD1). A summary of this risk assessment is provided below.

The food technology assessment concluded that this β-amylase is technologically justified and effective in achieving its stated purpose. It performs its technological purpose during manufacture 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.

Seven soybean proteins are listed as food allergens in the WHO/IUIS Allergen Nomenclature Database. β-Amylase from soybean is not one of these 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 the allergenic soybean 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 2.3.3.1.

Bioinformatic analysis identified a degree of amino acid sequence homology between β-amylase from soy and an allergenic protein from wheat. Clinically significant cross-reactivity between soybean allergy and wheat allergy has not been reported. Individuals with wheat allergy are not generally advised to avoid soy, or vice versa. A study of the risk of food allergy among soy-allergic consumers consuming wheat contaminated with low levels of soy noted a lack of evidence of allergic reactions among soy-allergic consumers to wheat-based products. In addition, exposure is likely to be very low and the enzyme is likely to be digested in the stomach like other dietary proteins. Based on the weight of evidence, FSANZ does not consider soybean β-amylase to be of allergenic concern in wheat allergic individuals.

Based on the available evidence FSANZ concluded that 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) of 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

Since the call for submissions, FSANZ has not been provided with any additional information to change its above assessment.

2.3 Risk management

From its risk assessment FSANZ concluded that there are no safety concerns relating to the use of the enzyme, β-amylase sourced from soybean as a food processing aid in the manufacture of maltose syrup. As processing aids require permissions in the Code, the main risk management options available to FSANZ, is to approve the draft variation proposed following assessment; approve the draft variation subject to such amendments that FSANZ considers necessary; or reject the draft variation. Other risk management issues for this application are related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in section 2.5.1.1 of this report take account of the safety of the enzyme.

2.3.1 Regulatory approval for enzymes

Based on its food technology assessment, FSANZ has concluded that this particular β-amylase meets its stated purpose as a processing aid in the manufacture of maltose syrup.

Based on its risk assessment, FSANZ has further concluded that in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for this 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 has decided to approve the draft variation proposed following assessment to permit the use of this enzyme as a processing aid for its stated purpose.

2.3.2 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 will be listed in the table to subsection in S18—9(3).[5]

2.3.3 Labelling requirements

In deciding to approve the draft variation, FSANZ notes that the generic exemption from listing processing aids in the statement of ingredients will apply to foods containing this processing aid.

2.3.3.1 Declaration of certain substances

As the enzyme is derived from soy, the risk assessment (section 3.3 of SD1 to this report) concluded that the enzyme preparation may contain traces of allergenic soybean proteins. When soy is present in a food for sale, including when present as an ingredient or component of a processing aid, it must be declared in accordance with Division 3 of Standard 1.2.3 (Information 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 (see subsection 1.2.3—4(4) and the table to section S9—3). However these exemptions do not apply to whey from soybean, which is the ingredient used during the production of this enzyme.

2.3.4 Risk management conclusion

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

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. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standards' development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory

[5] 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.

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

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

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for 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.

FSANZ, however, gave consideration to the costs and benefits that would arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (i.e. where the status quo is rejecting the application). This analysis considered allowing an already permitted enzyme, β-amylase (EC 3.2.1.2) from a new source, as a processing aid, for a particular technological purpose. The enzyme is derived from soybean (*Glycine max*).

The technological purpose of this β-amylase is use as a processing aid in starch processing to manufacture maltose syrup. This β-Amylase will be used as a processing aid at low levels and will either not be present in the final food or be 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 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 manufacture 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 manufacturers with a new enzyme preparation for use as a processing aid in starch processing to manufacture maltose syrup.

Due to the voluntary nature of the permission, manufacturers would only use β-amylase from

soybean (*Glycine max*) as a processing aid (enzyme) in starch processing to manufacture maltose syrup, 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. 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 was that the direct and indirect benefits that would arise from permitting β-amylase (EC 3.2.1.2) sourced from soybean (*Glycine max*) to be used as a processing aid (enzyme) in starch processing to manufacture maltose syrup, 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 in the Code apply in both Australia and New Zealand. There are no other relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (SD1) and concluded there were 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 purpose.

2.5.2.2 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 2.3.3 of this report above. Existing requirements for the declaration of certain foods and substances when present in food for sale will apply and enable consumers to make informed choices about the food.

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 has also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk 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**

There is no Codex Alimentarius general standard for enzymes (in contrast to the Codex General Standard for Food Additives). However, this 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 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 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 using β-amylase (EC 3.2.1.2) sourced from soybean (*Glycine max*) as a food processing aid in starch processing to manufacture maltose syrup. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the proposed 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[6]**

The Ministerial Policy Guideline Addition to Food of Substances other than Vitamins and Minerals[7] 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:

[6] Now referred to as the Food Ministers' Meeting
[7] http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals

- 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 β-amylase (EC 3.2.1.2) sourced from soybean (*Glycine max*) as a processing aid in starch processing to manufacture maltose syrup is consistent with the specific order principles for 'Technological Function'. All other requirements of the policy guidelines are similarly met.

3 References

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

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The United States Pharmacopeia (2018). Food Chemicals Codex 11th Edition, United States Pharmacopeial Convention, Rockville, MD. Accessed 14 September 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 A1204 – Beta-amylase from soybean (*Glycine max*) as a processing aid (enzyme)) 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 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 – 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 manufacture maltose syrup. 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[8], 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 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 manufacture 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 A1204 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 October 2020 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

[8] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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.