

**18 January 2016**  
**[01–16]**

## **Call for submissions – Application A1109**

### **Glutaminase from *Bacillus amyloliquefaciens* as a Processing Aid (Enzyme)**

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FSANZ has assessed an Application made by Amano Enzyme Inc. to permit glutaminase sourced from *Bacillus amyloliquefaciens* as a processing aid in the production of certain seasoning ingredients or food products used as seasonings and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

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

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, 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 and quicker 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](mailto: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) 29 February 2016**

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](mailto:standards.management@foodstandards.gov.au).

Hard copy submissions may be sent to one of the following addresses:

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## Supporting documents

The following document which informed the assessment of this Application is available on the FSANZ website at

<http://www.foodstandards.gov.au/code/applications/Pages/A1109Glutaminase.aspx>

SD1 Risk and Technical Assessment Report – Application A1109

## Executive summary

Amano Enzyme Inc submitted an Application seeking permission to use the enzyme glutaminase (EC number 3.5.1.2) sourced from *Bacillus amyloliquefaciens* as a processing aid. The Applicant states that this enzyme would be used in the production of certain seasoning ingredients (e.g. yeast extract, hydrolysed vegetable proteins and hydrolysed animal proteins) or food products used as seasonings (e.g. soy sauce, miso, vinegar, fish sauce, etc.).

Glutaminase catalyses the conversion of L-glutamine to glutamate, an important component of taste and quality in the foods to which glutaminase is added. The use of glutaminase to increase the glutamate content of these types of foods can be an alternative to use of chemicals (acid hydrolysis) or to external sources of glutamate (such as monosodium glutamate (MSG)), to form foods/food ingredients with high concentrations of glutamates.

Enzymes used in the production and manufacture of food are considered processing aids and are regulated by Schedule 18 in the *Australia New Zealand Food Standards Code*. Permitted enzymes of microbial origin are listed in the table to subsection S18—4(5).

The enzyme the Applicant wishes to use is sourced from a non-genetically modified strain of *B. amyloliquefaciens* (strain GT2). Strain GT2 is obtained by subjecting the parent strain, *B. amyloliquefaciens* (strain NP) to a conventional chemical mutation process. After undertaking a risk assessment, FSANZ concludes that there were no public health and safety issues associated with the source microorganism or with using the enzyme preparation as a food processing aid. Residual enzyme is expected to be present in the final food but would be inactive and susceptible to digestion like other dietary proteins. FSANZ also concludes that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' would be appropriate. A dietary exposure assessment was therefore not required.

The evidence presented to support the proposed uses 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 preparation meets international purity specifications.

FSANZ therefore proposes a draft variation to permit glutaminase as a processing aid. The nomenclature for the enzyme is consistent with the International Union of Biochemistry and Molecular Biology (IUBMB) naming system, the internationally recognised authority for enzyme nomenclature.

# 1 Introduction

## 1.1 The Applicant

The Applicant is Amano Enzyme Inc, Japan, a producer of specialty enzymes for pharmaceuticals, diagnostic medicines, and the food industry.

## 1.2 The Application

The purpose of the application is to seek permission to use the enzyme, glutaminase (EC number 3.5.1.2), as a processing aid. The enzyme would be used in the production of certain seasoning ingredients (e.g. yeast extract, hydrolysed vegetable proteins and hydrolysed animal proteins) or food products used as seasonings (e.g. soy sauce, miso, vinegar, fish sauce, etc.).

Glutaminase catalyses the conversion of L-glutamine present in these foods to glutamate, an important component of taste and quality in the foods to which glutaminase is added. The use of glutaminase to increase the glutamate content of foods can be an alternative to use of chemicals (acid or base hydrolysis) or to external sources of glutamate (such as monosodium glutamate (MSG)), to form foods/food ingredients with high concentrations of glutamates.

The enzyme is sourced from a chemically mutated strain of *Bacillus amyloliquefaciens* (strain GT2). The parent microorganism is classified as *B. amyloliquefaciens* strain NP. Strain GT2 is sourced from the NP strain by a conventional process mutation using *N*-methyl-*N'*-nitrosoguanidine. The strain is not genetically modified. Whilst glutaminase activity is present in *B. amyloliquefaciens*, strain GT2 is selected for its improved glutaminase production.

The glutaminase concentrate is sourced from *B. amyloliquefaciens* through a process of fermentation. After filtration and purification, the glutaminase concentrate is diluted with sodium chloride to produce an enzyme preparation containing 9% (w/w) glutaminase concentration. The trade name for the enzyme preparation is Glutaminase SD-C100S.

The Applicant reported that the enzyme preparation is inactivated either by changing the pH or the temperature of the food, thus ensuring that the enzyme has no function in the final food product. Guidelines for pH and temperature to achieve enzyme inactivation were provided in the Application.

## 1.3 The current Standard

All references to the *Australia New Zealand Food Standards Code* (the Code) in this assessment summary and related SDs are to the revised Code which takes effect and replaces the current Code on 1 March 2016. This is because the gazettal of any draft variation is not expected after this date, if approved by the FSANZ Board and no review of that decision is requested by Ministers, and FSANZ therefore considers it is unnecessary to amend the current Code.

Enzymes used in processing and manufacturing food are considered processing aids. Only those processing aids listed in Schedule 18 of the revised Code are permitted to be used in producing food sold in Australia and New Zealand. Permitted enzymes of microbial origin are listed in the table to subsection S18—4(5).

Currently there are no permissions for the enzyme glutaminase or enzyme with the EC number 3.5.1.2 in the revised Code. *B. amyloliquefaciens* is the host microorganism for ten other permitted enzymes in the Code.

If approved, the table to subsection S18—4(5) would refer to *B. amyloliquefaciens* without reference to the specific strain, as the Code does not normally identify microorganisms down to strains, just to species. Exceptions to this are where the properties belong to a particular strain only, or if there are significant safety or other considerations associated with that strain, which is not the current situation.

### **1.3.1 International Standards**

Codex Alimentarius does not have Standards for processing aids or enzymes. Individual countries regulate the use of enzymes differently to how they are regulated in the Code. However, there are internationally recognised specifications for enzymes. These enzyme specifications are provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2006) and the Food Chemicals Codex (Food Chemicals Codex, 2015).

The enzyme preparation Glutaminase SD-C100S has been permitted for use in food production in France (Saisine n° 2009-SA-0089 / Saisine liée no° 2009-SA-0330, July 16, 2009 (AFSSA, 2009)) and Japan, where it appears on the 'List of Existing Food Additives' published by the Ministry of Health and Welfare Japan (microbial source not specified) (MHLW, 2014).

## **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 might be developed as a food regulatory measure.

## **1.5 Procedure for assessment**

The Application is being assessed under the General Procedure.

# **2 Summary of the assessment**

## **2.1 Risk assessment**

There were no public health and safety issues associated with the use of the enzyme preparation Glutaminase SD-C100S, containing glutaminase sourced from a chemically mutated strain of *B. amyloliquefaciens*, as a food processing aid on the basis of the following considerations:

- The production organism is not toxigenic or pathogenic and is not present in the final enzyme preparation used as the food processing aid. Further, *B. amyloliquefaciens* has a history of safe use as the production organism for a number of processing aids already permitted in the Code.
- Glutaminase has a long history of safe use and although residual enzyme is expected to be present in the final food, it would be inactive and susceptible to digestion like any other dietary protein.

- Complete digestion of the enzyme in simulated digestive fluid suggests the enzyme is unlikely to be toxic.
- The enzyme preparation caused no observable adverse effects at the second-highest tested doses in a 13-week repeated dose toxicity study in rats. The NOAEL for the glutaminase concentrate was determined to be 0.6% w/w of the diet or 388 mg/kg bw/d (male rats) and 450 mg/kg bw/d (female rats).
- The enzyme is not genotoxic or mutagenic *in vitro*.
- Bioinformatic analysis indicated that the enzyme has no biologically relevant homology to known protein allergens. This means that the enzyme is not likely to be allergenic.

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

The evidence presented to support the proposed uses 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 preparation meets international purity specifications.

For further details on the risk assessment, refer to the Risk and Technical Assessment Report (SD1).

## **2.2 Risk management**

The risk assessment conclusions provided evidence that there are no safety risks from the use of this enzyme, sourced from *B. amyloliquefaciens*, as a processing aid. As processing aids require permissions in the Code, the only risk management options available to FSANZ are to approve or reject the request to amend the Code. The regulatory options analysed in section 2.4.1.1 take account of the safety of the enzyme preparation.

If permitted, the use of glutaminase will be one of a number of commercial methods available to increase the glutamate content of certain foods. The labelling considerations (section 2.2.2) below consider the risk management of the glutamates formed in these circumstances.

### **2.2.1 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 'glutaminase' for enzymes with an EC number of 3.5.1.2 (IUBMB, 2015). This is the name that is used in the proposed draft variation to the Code for this enzyme.

### **2.2.2 Labelling considerations**

As the risk assessment concludes that the use of the enzyme glutaminase poses no risk to public health and safety, FSANZ considers that the existing labelling requirements in the Code are appropriate for the use of the enzyme in foods.

As a general rule, processing aids are exempt from the requirement to be declared in the statement of ingredients in accordance with subsections 1.2.4—3(2)(d) and (e) of the revised Code. Therefore, the use of the enzyme glutaminase as a processing aid would not be declared on the label of the food.

As mentioned above, if permitted, the use of glutaminase will be one of a number of commercial methods used to increase the glutamate content of certain food products that already contain glutamate, namely seasoning ingredients (e.g. yeast extract or hydrolysed vegetable proteins) and food products used as seasonings (e.g. soy sauce). These types of food products are generally well-recognised for their characteristic savoury flavour that the high-glutamate content imparts.

There is no chemical difference between the glutamate that is naturally present in food (e.g. in tomatoes and meat), formed through the enzymatic conversion of L-glutamine, or that which is directly added to food as an ingredient or additive, and there is no difference in the body's physiological response.

As for other commercial methods currently used to increase the glutamate content of certain foods, the glutamate formed as a result of the enzymatic conversion of L-glutamine would not be declared on the label of the food. Individuals who may be intolerant to glutamates, or wish to avoid them, are likely to be aware that these certain food products contain glutamates and can continue to avoid these foods.

### **2.2.2.1 Mandatory declaration of certain substances**

Lactose, defatted soybean, soybean oil and dextrin (which may be produced from wheat starch) are raw materials used as fermentation media in the production of the enzyme.

The presence of these milk, soybean or wheat products in the final food as a component of the enzyme preparation would require mandatory declaration in accordance with section 1.2.3—4 (Information requirements – warning statements, advisory statements and declarations) of the revised Code.

## **2.3 Risk communication**

### **2.3.1 Consultation**

Consultation is a key part of FSANZ's standards development process.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on an application or proposal is considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

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 standard 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. Amending the Code to approve the enzyme, glutaminase, sourced from *B. amyloliquefaciens* as a processing aid is unlikely to have a significant effect on international trade as the enzyme preparation complies with international specifications for food enzymes provided by JECFA (JECFA, 2006) and the Food Chemicals Codex (9<sup>th</sup> Edition) (Food Chemicals Codex, 2015). 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 had regard to the following matters in section 29 of the FSANZ Act:

**2.4.1 Section 29**

**2.4.1.1 Cost benefit analysis**

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendments to the Code are analysed using regulatory impact principles. The level of analysis is commensurate with the nature of the Application and significance of the impacts.

Two regulatory options were considered:

- (1) prepare a draft variation to Schedule 18 to permit the use of the enzyme, glutaminase (EC number 3.5.1.2), sourced from *B. amyloliquefaciens* as a processing aid
- (2) reject the Application.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess if a Regulation Impact Statement is required for Applications relating to processing aids, as they are machinery in nature and their use is voluntary. However, FSANZ undertook a limited impact analysis.

A consideration of the costs and benefits of the regulatory options was not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the effects that were considered cannot be assigned a dollar value.

Rather, the assessment sought to highlight the qualitative effects of criteria that were relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

**Option 1 – Prepare a draft variation to Schedule 18**

Sector	Costs or benefits to sector
Consumers	There are no costs or benefits to consumers associated with this option. The use of glutaminase is one of a number of commercial methods available to increase the glutamate content of certain food products. The overall benefit to consumers, namely the availability of a range of food products with a distinctive ‘umami’ flavour is the same, irrespective of the method employed to achieve this result.



Sector	Costs or benefits to sector
Industry	<p>Glutaminase preparations already have a history of use as processing aids in the manufacture of certain food products. Glutaminase has been employed in the production of soy sauces since 1991 and in the production of miso since 1992 (Amano Enzyme, 2005). The use of glutaminase as a processing aid for the production of hydrolysed vegetable protein has been ongoing since 2003.</p> <p>The glutaminase preparation has benefits that include a high glutamate yield, excellent thermal stability, and stability during storage. A comparison of the glutaminase preparation against other methods for manufacturing certain food products indicates that there are a number of potential advantages including milder processing conditions and a desirable amino acid profile in the protein hydrolysates due to the specificity of the enzyme.</p>
Governments	There are no costs or benefits to governments associated with this option. <i>B. amyloliquefaciens</i> is the host microorganism for ten other permitted enzymes in the Code.

## Option 2 – Reject the Application

Sector	Costs or benefits to sector
Consumers	There are no benefits or costs to consumers of this option.
Industry	<p>There are no benefits to industry from this option. However, it is possible that there will be costs to industry, by not allowing them to use an alternative method for producing certain food products using this enzyme preparation.</p> <p>The glutaminase preparation has already been permitted for use and marketed in several other major jurisdictions (e.g. Europe and Japan). Therefore, it is possible that a cost to industry, particularly to overseas manufacturers and importers, will relate to their inability to expand the international trade of their products made using this enzyme preparation to Australia/New Zealand.</p>
Governments	There are no benefits or costs to governments for this option.

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweighed the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure. Therefore, the preferred option was to prepare a draft variation to Schedule 18.

### 2.4.1.2 Other measures

There were 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 applies in New Zealand and there are no relevant New Zealand only standards.

#### **2.4.1.4 Any other relevant matters**

See below.

#### **2.4.2 Subsection 18(1)**

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

##### **2.4.2.1 Protection of public health and safety**

FSANZ undertook a safety assessment (SD1) and concluded there were no public health and safety concerns relating to permitting the enzyme glutaminase sourced from *B. amyloliquefaciens* as a processing aid.

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

The labelling requirements for the enzyme processing aid are discussed in Section 2.2.2 – Labelling considerations. These requirements are considered to be appropriate for the permitted use of the enzyme in foods.

##### **2.4.2.3 The prevention of misleading or deceptive conduct**

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

#### **2.4.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk analysis which is provided in SD1. The Applicant submitted a dossier of scientific studies as part of their Application. Other technical information including scientific literature was also used in assessing the Application.

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

There are no Codex Alimentarius Standards for processing aids or enzymes. However, the enzyme preparation Glutaminase SD-C100S has been permitted for use in food production in France and Japan.

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

As mentioned above, the use of glutaminase sourced from *B. amyloliquefaciens* has a history of use in Europe and Japan. The Applicant expects that the introduction of glutaminase sourced from *B. amyloliquefaciens* to the Australia/New Zealand market will be well received. However, the food industry will make their own economic decisions, taking account of costs and benefits of using a new enzyme preparation to determine if it is of benefit to their business.

- **the promotion of fair trading in food**

The enzyme preparation has been assessed as safe and permitted for use in other countries. It is therefore appropriate that the local Australian and New Zealand food industries also benefit by gaining permission to use this same enzyme preparation.

- **any written policy guidelines formulated by the Ministerial Council<sup>1</sup>**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*<sup>2</sup> includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

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

FSANZ determined that permitting the use of the enzyme glutaminase sourced from *B. amyloliquefaciens* as a processing aid is consistent with the specific order policy principles for 'Technological Function'.

### 3 Draft variation

The draft variation to the revised 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 Legislative Instruments.

### 4 References

AFSSA (2009). *AVIS de l'Agence française de sécurité sanitaire des aliments relatif à une demande d'autorisation d'emploi sous deux formulations d'une glutaminase produite par une souche de Bacillus amyloliquefaciens non modifiée génétiquement pour la production d'hydrolysats de protéines et d'extraits de levures*. (AFSSA – Saisine n° 2009-SA-0089 / Saisine liée n° 2007-SA-0330, July 16, 2009). Maisons-Alfort, France: Agence Française de Sécurité Sanitaire des Aliments (AFSSA). Available at: <http://www.anses.fr/sites/default/files/documents/BIOT2009sa0089.pdf>.

Amano Enzyme (2005) [unpublished]. History of Uses [History of the Bacterial Strain for Glutaminase Production & History of Use of Glutaminase in Food] [Confidential]. (Appendix 9). Shiga, Japan: Amano Enzyme Inc.

Food Chemicals Codex 9<sup>th</sup> Edition (2015), The United States Pharmacopeia, United States Pharmacopeial Convention, Rockville, MD.  
<http://www.usp.org/food-ingredients/food-chemicals-codex>

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<sup>1</sup> Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

<sup>2</sup> <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

IUBMB (2015) EC 3.5.1.2. [http://www.enzyme-database.org/query.php?name=3.5.1.2&search=search\\_all&display=show\\_all&order=ec\\_num&nr=50](http://www.enzyme-database.org/query.php?name=3.5.1.2&search=search_all&display=show_all&order=ec_num&nr=50)

JECFA (2006) General specifications and considerations for enzyme preparations used in food processing. <http://www.fao.org/docrep/009/a0691e/A0691E03.htm>

MHLW (2014). List of existing food additives [compiled and published by the Ministry of Health and Welfare on April 16, 1996]. Japan Food Chemical Research Foundation (JFCRF), Tokyo, Japan. <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/listexst.add> [Effective from January 30, 2014, Last update: 06/30/2014].

## **Attachments**

- A. Draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)
- B. Draft Explanatory Statement

## Attachment A – Draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)



### Food Standards (Application A1109 – Glutaminase from *Bacillus amyloliquefaciens* 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 Standards Management Officer]

Standards Management Officer  
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 A1109 – Glutaminase from Bacillus amyloliquefaciens as a Processing Aid (Enzyme)) Variation*.

**2 Variation to a standard in the *Australia New Zealand Food Standards Code***

The Schedule varies a Schedule in the *Australia New Zealand Food Standards Code*.

**3 Commencement**

The variation commences on the date of gazettal.

**Schedule**

**[1] Schedule S18** is varied by inserting in the table to subsection S18—4(5), in alphabetical order

Glutaminase (EC 3.5.1.2)

*Bacillus amyloliquefaciens*

## **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.

FSANZ accepted Application A1109 which seeks to permit glutaminase sourced from *B. amyloliquefaciens* as a processing aid. The enzyme would be used in the production of certain seasoning ingredients or food products used as seasonings. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to the revised Code.

### **2. Purpose**

The purpose of this amendment is to permit the use of the enzyme, glutaminase, sourced from *B. amyloliquefaciens* as a processing aid. This requires an addition to the table to subsection S18—4(5) in Schedule 18 of the Code.

### **3. Documents incorporated by reference**

The variations to food regulatory measures do 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 A1109 will include one round of public consultation following an assessment and the preparation of a draft variation and associated report. A call for submissions (including the draft variation) will occur for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 18 is likely to have a minor impact on business and individuals.

### **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**

The variation inserts a new entry into the Table to subsection S18—4(5) in Schedule 18. The new entry would permit the use of glutaminase (EC number 3.5.1.2) sourced from *B. amyloliquefaciens* as a processing aid in food.