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[12–16]

Approval report – Application A1109

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

Food Standards Australia New Zealand (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.

On 18 January 2016, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 4 May 2016. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 17 May 2016.

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

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Supporting 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 (at Approval)

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 proteins¹ and hydrolysed animal proteins) or food products used as seasonings (e.g. soy sauce, miso, vinegar, fish sauce, etc.).

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.

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 under Schedule 18 in the *Australia New Zealand Food Standards Code* (the Code). Permitted enzymes of microbial origin are listed in the table to subsection S18—4(5).

FSANZ's risk assessment concluded 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 susceptible to digestion like other dietary proteins. FSANZ also concluded 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 provided adequate assurance that the enzyme, in the form described in the Application 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. Therefore, the assessment considered that the enzyme should be permitted for use 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.

The FSANZ Board has approved a draft variation to the table to subsection S18—4(5). This will permit the use of glutaminase (EC 3.5.1.2) sourced from *B. amyloliquefaciens* as a processing aid.

FSANZ received three submissions on the draft variation following the call for submissions, with all submitters supporting the draft variation. One submitter questioned whether consideration needed to be given to inform consumers who may be sensitive to glutamate. As for other commercial methods currently used to increase the glutamate content of certain foods, the provision of information to consumers on the glutamate content of the food e.g. through labelling, would not be required.

¹ Hydrolysed vegetable protein is a savoury ingredient. It is produced by treating a protein obtained from a plant source with an acid (in a chemical process known as acid hydrolysis), to break the protein down into its component parts (amino acids), including glutamate.

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 Application was received on 12 February 2015.

The purpose of the application was 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 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

Enzymes used in processing and manufacturing food are considered processing aids. Only those processing aids listed in Schedule 18 of the 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 Code. *B. amyloliquefaciens* is the host microorganism for ten other permitted enzymes in the Code.

The FSANZ Board has approved a draft variation to the table to subsection S18—4(5). The draft variation refers 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.

1.4 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 was assessed under the General Procedure.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Three submissions on the draft variation were received – two from government departments (one Australian; one New Zealand) and one from a food industry association. The draft variation to Standard 1.3.3 was supported by all submitters.

Submitters were satisfied that the use of the enzyme is technologically justified and that there were no public health or safety concerns identified during FSANZ's safety assessment of the enzyme preparation and source microorganism.

One submitter questioned whether consideration needed to be given to inform consumers who may be sensitive to glutamate. The use of glutaminase is only one of several commercial methods available to increase the glutamate content of certain foods such as seasoning ingredients, which already have high concentrations of glutamates (through fermentation and/or other naturally occurring hydrolytic processes). As for these other commercial methods, the provision of information to consumers on the glutamate content of the food e.g. through labelling, would not be required.

2.2 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 susceptible to digestion like any other dietary protein.
- Complete digestion of the enzyme in simulated digestive fluid suggests the enzyme is unlikely to be an allergen.

- Bioinformatic analysis² indicated that the enzyme has no biologically relevant homology to known protein allergens. This means that the enzyme is not likely to be allergenic.
- Although there was a reduction in weight gain and feed consumption at the highest dose tested in a 13-week repeat dose toxicity study in rats, this reduction was considered to be due to palatability of the feed containing high levels of common table salt. Thus, in the absence of any treatment related adverse effects, the NOAEL (No-Observed-Adverse-Effect Level) for the glutaminase concentrate was considered to be at the highest dose tested, which was 2% (w/w) in the diet or 1239 mg/kg bw/day.
- The enzyme was not genotoxic or mutagenic *in vitro*.
- 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 provided adequate assurance that the enzyme, in the form and prescribed amounts, was technologically justified and was 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).

2.3 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 were to approve or reject the request to amend the Code.

Additionally, as discussed below, the risk management evaluation considered international standards, the appropriate enzyme nomenclature, the applicability of the labelling provisions in the Code, and an analysis of benefits and costs.

2.3.1 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).

² In the context of this Report, this is the analysis of biological data (in this case data on molecular genetics) using computers, to determine whether there are any biologically significant similarities with known protein allergens, as one means of assessing the safety of the enzyme.

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 'glutaminase' for enzymes with an EC number of 3.5.1.2 (IUBMB, 2015). FSANZ used this name for the drafting for the Code (see Attachment A).

2.3.3 Labelling considerations

Processing aids are, in most cases, 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 Code. Therefore, the use of the enzyme glutaminase as a processing aid would not be declared on the label of the food. As the risk assessment has concluded that there are no public health and safety concerns relating to the use of the enzyme glutaminase as a processing aid, FSANZ considers that the existing exemption in the Code is appropriate for the use of the enzyme in foods.

The use of glutaminase is 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.

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.

2.3.3.1 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 processing aid would require mandatory declaration in accordance with section 1.2.3—4 (Mandatory declaration of certain foods or substances in food) of the Code.

2.3.4 Cost benefit analysis

FSANZ undertook a basic cost benefit analysis for this Application and concluded that permitting the use of glutaminase sourced from *B. amyloliquefaciens* as a food processing aid had benefits to the food industry, including manufacturers of seasoning ingredients and food products used as seasonings. The benefits included a high glutamate yield, excellent thermal stability, and stability during storage. A comparison of the glutaminase preparation against other methods for increasing the glutamate content of certain foods indicated that there were a number of potential advantages. These were milder processing conditions and a desirable amino acid profile in the protein hydrolysates due to the specificity of the enzyme. There were no costs to different stakeholders that overrode these benefits. There were no benefits in rejecting the Application.

FSANZ concluded that 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 and industry that would arise from the development or variation of such a food regulatory measure.

2.3.5 Risk management conclusion

The proposed use of glutaminase sourced from *B. amyloliquefaciens* as a processing aid, in its prescribed form and usage, is technologically justified. The risk assessment conclusions indicated that there were no public health and safety risks associated with its use. The glutaminase preparation has already been permitted for use and marketed in several other major jurisdictions (e.g. Europe and Japan). The basic cost benefit analysis indicated that the benefits accrued from permitting the use of this enzyme would outweigh any costs. Based on this information, the preferred risk management option was to prepare a draft variation to Schedule 18 of the Code.

3 Decision

The draft variation as proposed following assessment was approved without change and is at Attachment A. The 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.

4 Risk communication

4.1 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 was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment. FSANZ called for public comment between 18 January 2016 and 4 March 2016 after assessing the Application. All three submissions that were received supported the draft variation.

FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

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

The FSANZ Board considered the draft variation taking into account comments received from the call for submissions.

The Applicant, individuals and organisations that made submissions on this Application were notified at each stage of the assessment. Subscribers and interested parties were also notified via email about the availability of reports for public comment.

The FSANZ Board's decision has been notified to the Australia and New Zealand Ministerial Forum on Food Regulation. If the decision is not subject to a request for a review by Ministers, the Applicant and stakeholders will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

5 FSANZ Act assessment requirements

5.1 Section 29

5.1.1 Cost benefit analysis

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. In any case, FSANZ conducted a basic cost analysis, which is described in Section 2.3.4 above.

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.

5.1.3 Any relevant New Zealand standards

Schedule 18 applies to New Zealand and there are no relevant New Zealand only Standards.

5.1.4 Any other relevant matters

Other relevant matters are considered below.

5.2 Subsection 18(1)

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

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 relating to permitting the enzyme glutaminase sourced from *B. amyloliquefaciens* as a processing aid.

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

The labelling approach for the enzyme processing aid is discussed in Section 2.3.3 above. The existing provisions in the Code are considered to be appropriate for the permitted use of the enzyme in foods.

5.2.3 The prevention of misleading or deceptive conduct

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

5.3 Subsection 18(2) considerations

FSANZ also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk analysis which is provided in SD1 – the Risk and Technical Assessment Report. 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**

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 was 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 Forum on Food Regulation**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*³ 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 was consistent with the specific order policy principles for 'Technological Function'.

³ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

6 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>.

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

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

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. 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 A1109 – Glutaminase from *Bacillus amyloliquefaciens* 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 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 – 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 sought to permit glutaminase sourced from *Bacillus amyloliquefaciens* (*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 prepared a draft variation to the Code.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, 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 sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved the use of the enzyme, glutaminase, sourced from *B. amyloliquefaciens* as a processing aid. This required an addition to the table to subsection S18—4(5) in Schedule 18 of the Code.

3. Documents incorporated by reference

The variation to food regulatory measures 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 A1109 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 18 January 2016 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Schedule 18 are 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.