

21 September 2016
[23–16]

Call for submissions – Application A1121

Oryzin (Protease) from *Aspergillus melleus* as a Processing Aid (Enzyme)

FSANZ has assessed an Application made by Amano Enzyme Inc. to permit the use of Oryzin (protease) from *Aspergillus melleus* as an enzyme for use in baking, flavouring production and dairy, egg, meat, fish, protein and yeast processing 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 we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient 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.

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) 2 November 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. Hard copy submissions may be sent to one of the following addresses:

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Supporting document

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/A1121Oryzin\(Protease\)asaPA.aspx](http://www.foodstandards.gov.au/code/applications/Pages/A1121Oryzin(Protease)asaPA.aspx)

SD1 Risk and technical assessment report

Executive summary

Amano Enzyme Inc., a Japanese enzyme manufacturer, has submitted an application to amend Schedule 18 in the *Australia New Zealand Food Standards Code* (the Code) to permit the use of a new enzyme, Oryzin (protease) from *Aspergillus melleus*, as a processing aid.

Enzymes used in processing and manufacturing food are considered processing aids. Oryzin (protease) from *A. melleus* is intended for use in baking, dairy, egg, meat, fish and yeast processing, protein processing and flavouring production. Only processing aids listed in Schedule 18 are permitted to be used in producing food sold in Australia and New Zealand. There are no current permissions in Schedule 18 for an enzyme processing aid produced using *A. melleus*.

FSANZ has determined that the evidence presented in the Application provides adequate assurance that the enzyme, in the form and prescribed amounts, is technologically justified to be effective in achieving its stated purpose. The enzyme preparation meets international purity specifications for enzymes used in the production of food.

Also, FSANZ's assessment concludes that there are no public health and safety issues associated with the use of the enzyme preparation containing Oryzin produced by mutated *A. melleus* (strain P-52), as a food processing aid. Based on the reviewed toxicological data, it is concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate. Therefore a dietary exposure assessment has not been undertaken.

In addition, information regarding the identity of the enzyme provided by the Applicant has been verified using the appropriate internationally accepted reference for enzyme nomenclature. Also, as the risk assessment concludes that the use of the enzyme Oryzin from *A. melleus* poses no risk to public health and safety, the existing labelling requirements in the Code are considered to be appropriate.

FSANZ has considered the potential impacts of approving this Application on consumers, the food industry, and enforcement agencies. FSANZ considers that benefits that would arise from permitting the use Oryzin (protease) from *A. melleus* as a processing aid would outweigh the costs. FSANZ also considers that this permission is consistent with the relevant Ministerial Policy Guidelines. Therefore, a draft variation to amend Schedule 18 has been prepared.

1 Introduction

1.1 The Applicant

Amano Enzyme Inc., Nagoya, Japan Enzyme manufacturer.

1.2 The Application

The Application seeks to amend Schedule 18 in the *Australia New Zealand Food Standards Code* (the Code) to permit the use of a new enzyme, Oryzin (Protease) from *Aspergillus melleus*, as a processing aid. The processing aid is intended for use in baking, dairy processing, egg, meat, fish and yeast processing, protein processing and flavouring production.

There are no current permissions in Schedule 18 for an enzyme processing aid produced using *A. melleus*.

The effect of the enzymatic conversion (using Oryzin) is the conversion of the substrate proteins and peptides in various food raw materials, which may result in improvement of organoleptic properties (taste and flavour), physiological properties (foaming ability, emulsifying ability, heat stability, and viscosity) and nutritional properties (absorptivity, digestibility).

1.3 The current Standard

1.3.1 Standard 1.3.3 and Schedule 18

Enzymes used in processing and manufacturing food are considered processing aids, regulated under Standard 1.3.3 in the Code. Only those processing aids listed in Schedule 18 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). There are no current permissions in Schedule 18 for an enzyme processing aid produced using *A. melleus*.

1.3.2 International Standards

Codex Alimentarius does not have specific Standards for processing aids or enzymes, and individual countries regulate the use of enzymes differently to 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 Applicant notes that the following national and international standards are relevant:

- protease is listed on the Food Additive Index of CODEX General Standard for Food Additives (GSFA) (INS: 1101(i)).
- this food enzyme, Oryzin (Protease), complies with the internationally accepted JECFA specifications for chemical and microbiological purity of food enzymes (FAO/WHO, 2006)
- protease (exopeptidase) from *A. melleus* is approved in France and Denmark
- protease from *A. melleus* is on the “List of Existing Food Additives” published by the Ministry of Health and Welfare of Japan (MHLW, 2014)
- protease from *A. melleus* is approved as a food additive in China
- protease from *A. melleus* is on a list of Permitted Food Enzymes of Health Canada.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- 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 and technical assessment

A1121 seeks approval to use the enzyme Oryzin, sourced from a mutated strain of *A. melleus* (strain P-52), as a processing aid. Oryzin is a serine endopeptidase which can catalyse the hydrolysis of proteins with broad specificity, but does not hydrolyse peptide amides. The Applicant states that the enzyme will be used in flavourings, cereal products produced from flour, enzyme modified cheese or dairy ingredients used in other foods, processed egg products, and in products such as dressings and sauces, meat and fish extracts, and protein hydrolysates and yeast extracts used in other foods.

The evidence presented to support the proposed uses provides adequate assurance that the enzyme, in the form and prescribed amounts, is technologically justified to be effective in achieving its stated purpose. The enzyme preparation meets international purity specifications for enzymes used in the production of food.

There are no public health and safety issues associated with the use of the enzyme preparation containing Oryzin produced by mutated *A. melleus* (strain P-52), as a food processing aid on the basis of the following considerations:

- The production organism is not toxigenic or pathogenic. Further, *A. melleus* has a long history of safe use overseas as the production organism for a number of processing aids.
- Residual Oryzin is expected to be present in the final food but recommended conditions for use would render the enzyme inactive and it would be susceptible to digestion like any other dietary protein.
- Bioinformatics analysis indicated that Oryzin has no biologically relevant homology to known food protein allergens.
- The Oryzin preparation caused no observable effects at the highest tested doses in a 26-week repeated dose toxicity study in rats. The No Observable Adverse Effect level (NOAEL) for the Oryzin concentrate was determined to be 2000 mg/kg body weight/day for male rats.
- The enzyme was not genotoxic *in vitro*.

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

The Application states that soy and wheat products (flour and bran) are used in the fermentation media. The Applicant also notes that 'residual soy and wheat allergens are not present in Oryzin (Protease) enzyme powder (less than 3.0µg/g)'.

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

2.2 Risk management

The risk assessment conclusions provide evidence that there are no safety risks from the use of this enzyme as intended. As processing aids require permissions in the Code, the main risk management options available to FSANZ are either to approve or reject the request to amend the Code. These options are considered in section 2.4.1.1 and take account of the safety of the enzyme preparation. Other risk management issues relate to enzyme nomenclature and labelling as discussed below.

2.2.1 Enzyme nomenclature

Information regarding the identity of the enzyme provided by the Application has been verified using the appropriate internationally accepted reference for enzyme nomenclature, the International Union of Biology and Molecular Biology (IUBMB 2016). The accepted IUBMB name is Oryzin, for enzymes with an EC1 number 3.4.21.63 (see SD1). Therefore this would be the name used for this enzyme in the Code.

If approved, the table to subsection S18—4(5) would refer to Oryzin (Protease) sourced from *A. melleus* 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. This is not the current situation in the Application.

2.2.2 Labelling considerations

As the risk assessment concludes that the use of the enzyme Oryzin from *A. melleus* poses no risk to public health and safety, FSANZ considers that the existing labelling requirements in the Code are appropriate for the labelling of foods produced using Oryzin as a processing aid.

As a general rule, processing aids are exempt from the requirement to be declared in the statement of ingredients in accordance with paragraphs 1.2.4—3(2)(d) and (e) of Standard 1.2.4 – Information requirements – statement of ingredients.

Soybean and wheat products are used in the fermentation medium in the production of Oryzin. Soybeans and cereals containing gluten are required to be declared if present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid (section 1.2.3—4 of Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations).

Food manufacturers selling food made with Oryzin as a processing aid need to ensure compliance with allergen declarations where required in accordance with Standard 1.2.3.

¹ EC: Enzyme Commission, internationally recognised number that provides a unique identifier for the enzyme

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process is open, accountable, consultative and transparent. Public submissions are called for to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

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

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

Following this round of public consultation, the draft variation will be considered for approval by the FSANZ Board, taking into account comments received in 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 for processing aids or enzymes. Amending the Code to approve the enzyme Oryzin, sourced from *A. melleus*, 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 (9th 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 has had regard to the following matters in section 29 of the FSANZ Act, as follows.

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 for this Application:

- (1) prepare a draft variation to Schedule 18 to permit the use of the enzyme Oryzin, sourced from *A. melleus* 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 has undertaken a limited impact analysis.

This consideration of the costs and benefits of the above options is not intended to be an exhaustive, quantitative economic analysis and, in fact, most of the effects considered cannot be assigned a dollar value.

Rather, the assessment aims to highlight the qualitative effects that are relevant to each option. These considerations are deliberately limited to broad areas such as trade, consumer information and compliance.

Option 1 – Prepare a draft variation to Schedule 18

For consumers, there are no costs associated with this Option. On the other hand, the applicant notes the use of the enzyme Oryzin sourced from *A. melleus* as a processing step in food production, may result in improvement of organoleptic properties (taste and flavour) and nutritional properties (absorptivity and digestibility) which may provide some benefit to consumers.

For the food industry, the Applicant notes that the use of this enzyme in food processing may result in improvement of physiological properties (foaming ability, emulsifying ability, heat stability, viscosity), as well as the properties noted above, which could benefit food manufacturers. As it is a voluntary permission, any costs to food manufacturers would be by choice.

For Government agencies, no costs or benefits are likely as a result of this option.

Option 2 – Reject the Application

Any of the benefits noted under Option one would not be gained if the status quo was maintained.

Overall, the direct and indirect benefits that would be gained if this Application was approved would outweigh any costs to the community, Government or industry. Therefore, the preferred option is to prepare a draft variation to Schedule 18.

2.4.1.2 Other measures

FSANZ considers there no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed as a result of this Application.

2.4.1.3 Any relevant New Zealand standards

There are no relevant New Zealand Standards. Standard 1.3.3 and Schedule 18 apply to both Australia and New Zealand.

2.4.1.4 Any other relevant matters

Other relevant matters are covered below.

2.4.2. Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (SD1) and concludes that there are no public health and safety concerns associated with the use of the enzyme preparation containing Oryzin produced by mutated *A. melleus* (strain P-52) as a food 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. The existing labelling requirements in the Code 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

No issues have been 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 Oryzin from *A. melleus* is permitted for use in France, Denmark, Japan, China, and Canada (see section 1.3.1).

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

As mentioned above, the use of Oryzin from *A. melleus* has a history of use in other countries. The Applicant expects that the introduction of this enzyme to the Australia/New Zealand market will provide benefits to food manufacturers and importers.

However, it is expected that 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 is permitted for use in other countries. It is therefore appropriate that the local Australian and New Zealand food industries can 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*² 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 with regard to the substance.

FSANZ considers that permitting the use of the enzyme Oryzin, from *A. melleus* as a processing aid, is consistent with the specific order policy principles for 'Technological Function'.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

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

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1121 – Oryzin (Protease) from *Aspergillus melleus* 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 A1121 – Oryzin (Protease) from Aspergillus melleus 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 18 is varied by adding the following to the table to subsection S18—4(5), in alphabetical order

Oryzin (EC 3.4.21.63)

Aspergillus melleus

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 A1121 which seeks to permit the use of Oryzin (protease) from *Aspergillus melleus* as an enzyme for use in baking, flavouring production and dairy, egg, meat, fish, protein and yeast processing. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The Authority has prepared an amendment to the Code to permit the use of the enzyme, Oryzin (EC³ number 3.4.21.63) sourced from *A. melleus* as a processing aid. This requires an addition to the table to subsection S18—4(5) in Schedule 18.

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 A1121 will include one round of public consultation following an assessment, and the preparation of a draft amendment to the Code and associated report.

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 Code is varied (amended) by inserting a new entry into the table to subsection S18—4(5) in Schedule 18 to permit the use of Oryzin (EC number 3.4.21.63) sourced from *A. melleus* as a processing aid in food.

³ EC: Enzyme Commission, internationally recognised number that provides a unique identifier for the enzyme