

23 March 2017
[08–17]

Approval report – Application A1121

Oryzin (Protease) 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.

On 21 September 2016, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 9 March 2017. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 22 March 2017.

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 document

The [following document](#)¹ which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and technical assessment report (at Approval)

¹ [http://www.foodstandards.gov.au/code/applications/Pages/A1121Oryzin\(Protease\)asaPA.aspx](http://www.foodstandards.gov.au/code/applications/Pages/A1121Oryzin(Protease)asaPA.aspx)

Executive summary

Amano Enzyme Inc., a Japanese enzyme manufacturer, 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 a mutated strain of *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 permissions in the current Schedule 18 for an enzyme processing aid produced using *A. melleus*.

After consideration of the available evidence, FSANZ is satisfied that Oryzin (protease), in the form and prescribed amounts, is technologically justified to be effective in achieving its stated purpose. The enzyme preparation² meets international purity specifications for enzymes used in producing food.

FSANZ's assessment concluded that there are no public health and safety concerns associated with using the enzyme preparation containing Oryzin (protease)³ produced from *A. melleus* (strain P-52), as a food processing aid. Therefore, a draft variation to Schedule 18 to include Oryzin (protease) from *A. melleus* as a processing aid has been approved. Because the Code normally identifies microorganisms at the species⁴ level, not to the strain, the table to subsection S18—4(5) will refer to Oryzin (Protease) sourced from *A. melleus* without reference to the specific strain.

Information about the identity of the enzyme provided by the Applicant was verified using the appropriate internationally accepted reference for enzyme nomenclature. Also, as the risk assessment concluded that the use of the enzyme poses no risk to public health and safety, existing labelling requirements in the Code are considered to be appropriate and adequate.

FSANZ considered that permitting Oryzin (protease) from *A. melleus* as a processing aid would provide a net benefit to the community. FSANZ also considered that the variation is consistent with the relevant Ministerial Policy Guidelines. All three submitters to the Call for Submissions supported the proposed variation.

² Production of the enzyme preparation is described in Supporting Document1.

³ Oryzin is characterised as a serine endopeptidase (or serine protease). See Supporting Document 1.

⁴ 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 situation in this Application.

1 Introduction

1.1 The Applicant

Amano Enzyme Inc., Nagoya, Japan Enzyme manufacturer.

1.2 The Application

The Application sought to amend Schedule 18 – Processing aids in the *Australia New Zealand Food Standards Code* (the Code) to permit the use of a new enzyme, Oryzin (Protease) mutated⁵ 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.

Using Oryzin converts 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 and are regulated in Standard 1.3.3 – Processing aids. 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 other countries regulate the use of enzymes differently to the Code. However, there are internationally recognised specifications for enzymes. These 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 noted 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)).
- 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.

⁵ See SD1 section 3.2

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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed after assessment was approved without change after considering submissions. The approved variation is at Attachment A and takes effect on the date of gazettal.

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ received three submissions in response to a public call for submissions, and all three supported varying Schedule 18 to permit the use of the enzyme Oryzin, sourced from *A. melleus* as a processing aid. No issues were raised.

2.2 Risk assessment

FSANZ assessed evidence, including that presented to support the proposed uses of the enzyme Oryzin, and concluded that it 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.

No public health and safety issues were identified with using the enzyme preparation containing Oryzin produced from *A. melleus* (strain P-52), as a food processing aid, based on the following considerations:

- The production organism is not toxigenic or pathogenic, and is not listed⁶ as a species that produces an allergen (see SD1). Also, it does not remain in the final enzyme preparation used in food production. In addition, *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.

⁶ <http://www.allergenonline.org/databasebrowse.shtml>

- Bioinformatics analysis indicated that Oryzin has no biologically relevant homology to known food protein allergens, so does not raise allergenicity concerns if ingested as a processing aid in food.
- It is further noted that the level of the enzyme protein in the final food is likely to be very low and the effects of food processing and digestion in the gastrointestinal tract by pepsin are also likely to reduce the risk of potential enzyme allergenicity. Overall, the risk of allergenicity through the ingestion of oryzin added to various food products as a processing aid is considered to be very low.
- 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, FSANZ concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate. A dietary exposure assessment was therefore not undertaken.

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

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

2.3 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 were either to approve or reject the request to amend the Code, taking account of the safety of the enzyme preparation. Other risk management considerations relate to enzyme nomenclature and labelling as discussed below.

2.3.1 Enzyme nomenclature

Information about the identity of the enzyme provided in 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 variation reflects the accepted IUBMB name is Oryzin, for enzymes with an EC⁷ number 3.4.21.63 (see SD1).

Because the Code normally identifies microorganisms at the species⁸ level, not to the strain, the table to subsection S18—4(5) will refer to Oryzin (Protease) sourced from *A. melleus* without reference to the specific strain.

⁷ EC: Enzyme Commission, internationally recognised number that provides a unique identifier for the enzyme

⁸ 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 situation in this Application.

2.3.2 Labelling considerations

As the risk assessment concluded that using 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.

The Code (section 1.2.3—4(b) of Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations) requires the mandatory declaration of certain known allergens. Soybean and wheat products are used in the fermentation medium in producing Oryzin. Soybeans and cereals containing gluten must be declared when present as an ingredient, an ingredient of a compound ingredient, or as a food additive or processing aid (including when used as an ingredient or component of these).

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

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. Public submissions on a proposed draft variation to Schedule 18 were called for from 21 September to 2 November 2016.

The call for submissions was notified through a media release, Food Standards News and through FSANZ's social media channels.

Three submissions were received; two from government jurisdictions and one from the food industry. All comments were considered by the FSANZ Board. FSANZ acknowledges the time taken by these organisations as all comments received contribute to the rigour of our assessment.

2.5 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.

2.5.1 Section 29

2.5.1.1 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 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.

The consideration of the costs and benefits of the variation was not intended to be an exhaustive, quantitative economic analysis and, most of the effects considered cannot be assigned a dollar value.

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

For consumers, there are no costs associated with the variation to the Code. The Applicant noted that 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 noted 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 mentioned 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.

Overall, FSANZ considers the direct and indirect benefits gained by the variation would outweigh any costs to the community, government or industry.

2.5.1.2 Other measures

No other measures (whether available to FSANZ or not) would be more cost-effective than the variation.

2.5.1.3 Any relevant New Zealand standards

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

2.5.1.4 Any other relevant matters

Other relevant matters considered are outlined below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

The Risk and Technical Assessment (SD1) concluded that there are no public health and safety concerns associated with using the enzyme preparation containing Oryzin produced by *A. melleus* (strain P-52) as a food processing aid.

2.5.2.2 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 2.3.2. The existing labelling requirements in the Code are considered to be appropriate and adequate for the permitted use of the enzyme in foods.

2.5.2.3 The prevention of misleading or deceptive conduct

No issues were 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 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 1.3.2).

- **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 introducing this enzyme to the Australia and New Zealand market will provide benefits to food manufacturers and importers. Its uptake will be a commercial matter for businesses.

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

The enzyme preparation was assessed as safe, and is permitted for use in other countries. Gaining permission to use this same enzyme preparation could provide trade benefits for local Australian and New Zealand food industries.

- **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](#)⁹ 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.

⁹ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

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'.

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 A1121 – Oryzin (Protease) 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) 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 – 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 A1121 which sought 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 approved a draft variation.

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 an amendment to the Code to permit the use of the enzyme, Oryzin (EC 3.4.21.63¹⁰) sourced from *Aspergillus melleus* as a processing aid in food. 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 included one round of public consultation following an assessment and preparation of a draft variation and associated report. Submissions were called for on 21 September 2016 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.

¹⁰ EC: Enzyme Commission, internationally recognised number that provides a unique identifier for the enzyme

6. Variation

Item 1 of the variation amends Schedule 18 by inserting the following new entry into the table to subsection S18—4(5): Oryzin (EC 3.4.21.63) sourced from *Aspergillus melleus*. The effect of this amendment is to permit that enzyme's use as a processing aid in food.