

20 July 2017
[19–17]

Call for submissions – Application A1131

Aqualysin 1 (Protease) as a Processing Aid (Enzyme)

FSANZ has assessed an Application made by Puratos NV to permit the use of aqualysin 1 sourced from *Bacillus subtilis*, containing the aqualysin 1 gene from *Thermus aquaticus*, for use as a processing aid in the manufacture of bakery products, 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 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 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) 31 August 2017

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

SD1 Risk and technical assessment report

¹

<http://www.foodstandards.gov.au/code/applications/Pages/A1131%20Aqualysin%201%20protease%20as%20a%20PA.aspx>

Executive summary

Puratos NV (Belgium) submitted an Application seeking permission for the enzyme, aqualysin 1 (a protease enzyme) to be added to the list of permitted processing aids in the *Australia New Zealand Food Standards Code*.

Proteases are used in the baking industry to hydrolyse proteins in flour to smaller peptides and amino acids, which changes the characteristics of the dough. The Applicant claims the enzyme will result in faster dough development, better machinability and improved dough structure.

Enzymes used to produce and manufacture food are considered processing aids and are regulated by Standard 1.3.3 – Processing Aids. Permitted enzymes as processing aids are listed in Schedule 18.

After undertaking a risk assessment, FSANZ has concluded that there are no public health and safety concerns associated with using the enzyme preparation as a food processing aid in bakery products. Residual enzyme may be present in the final food but would be inactive and 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' is 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, is technologically justified and has been demonstrated to be effective in achieving its stated purpose and performing its technological function as a processing aid for use in the manufacture of bakery products. The enzyme preparation meets international purity specifications.

The Application requested an amendment to the Code to include the enzyme in section S18—4 (permitted enzymes). The enzyme is proposed to be used specifically in the manufacture of bakery products and, as such, information supplied in the Application and assessed by FSANZ was consistent with that stated purpose. On this basis, FSANZ is proposing to limit the permission to the stated purpose.

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the name aqualysin 1 for enzymes with an EC number of 3.4.21.111. This is the name used in the Application and in this summary.

1 Introduction

1.1 The Applicant

The Applicant is Puratos NV (Belgium), a company specialising in developing, producing, distributing and marketing raw materials for the bakery, confectionery, chocolate and catering industry, which includes the production and distribution of enzymes for these industries.

1.2 The Application

The Application sought permission for aqualysin 1 (protease) (Enzyme Commission (EC) number 3.4.21.111) sourced from *Bacillus subtilis* containing the aqualysin 1 gene from *Thermus aquaticus* as a processing aid. The source microorganism is genetically modified.

Aqualysin 1 will be used to manufacture bakery products. Proteases are used in the baking industry to hydrolyse proteins present in flour to smaller peptides and amino acids, which changes the characteristics of the resulting dough. The Applicant claims the use of aqualysin 1 has benefits including:

- faster dough development and better dough machinability
- improved structure and extensibility of the dough.

1.3 The current Standard

Enzymes used to produce and manufacture food sold in Australia and New Zealand are considered processing aids (Standard 1.3.3 of the *Australia New Zealand Food Standards Code* (the Code)). Only those enzymes listed in Schedule 18 – Processing Aids in 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) in Schedule 18, while some may be also permitted in the table to subsection S18—9(3) with the technological purpose being for the production of certain foods.

The permissions to use enzymes as processing aids is derived from the definition of ‘used as a processing aid’ in section 1.1.2—13 and repeated in section 1.3.3—2 (extract provided below).

In this Code, a reference to a substance that is **used as a processing aid** in relation to a food is a reference to a substance that is used during the course of processing:

- (a) to perform a technological purpose in the course of processing; and
- (b) does not perform a technological purpose in the food for sale; and

There is currently no permission for aqualysin 1 or any enzyme name with EC number 3.4.21.111 in Schedule 18. There are permissions for enzymes which have an EC number of 3.4.21.xx (group called serine peptidases) being; endo-protease (EC 3.4.21.26), serine proteinase (EC 3.4.21.14) and trypsin (EC 3.4.21.4). FSANZ has completed its assessment of Application A1121 from Amano Enzymes Inc. for another serine peptidase, oryzin (EC 3.4.21.64).

The source microorganism for the aqualysin 1 is a genetically modified *B. subtilis*. The host, *B. subtilis*, is a host or source organism for a number of permitted enzymes. The donor organism for the *aqualysin 1* gene is *T. aquaticus*, which is not a source organism for other permitted enzymes.

1.3.1 International Standards

The enzyme preparation has been approved for use in food production in Canada, France and the USA.

The Codex Alimentarius does not establish Standards for processing aids or for enzymes. Individual countries regulate the use of enzymes differently to the Code.

However, there are internationally recognised specifications for enzymes. These enzyme specifications are established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA 2006) and the Food Chemicals Codex (Food Chemicals Codex 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 warranted the variation of 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

FSANZ conducted a risk assessment on the proposed use of the enzyme. The assessment is provided at supporting document 1 and its conclusions are summarised below.

The stated purpose of this enzyme preparation, namely, for use as a processing aid in the manufacture of bakery products, is clearly articulated in the Application. 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. That is, it performs its technological purpose during processing and manufacture of food and does not perform a technological purpose in the final food since it is inactivated. It is therefore appropriately categorised as a processing aid and not a food additive. FSANZ notes that the quantity of aqualysin 1 used in bakery products is limited by the fact that if it is used in excess, it causes poor structure of the bread. The enzyme preparation meets international purity specifications.

B. subtilis is not pathogenic or toxigenic, and has a well-established history of use for production of enzymes used as food processing aids. Aqualysin 1 is in use as a food processing aid in France, Canada and the USA.

There is no evidence that aqualysin 1 is genotoxic, and it was well-tolerated by rats in a 13-week repeat-dose oral gavage study. The No Observed Adverse Effect level (NOAEL) in that study was 38,400 mU²/kg bodyweight(bw)/day, equivalent to 606 mg TOS (Total Organic Solids)/kg bw/day. In contrast, the Theoretical Maximum Daily Intake of aqualysin by a European consumer of very large amounts of bread (90 kg/year) is calculated to be 0.6229 mg TOS/kg bw/day, almost 1000-fold less.

² Units of enzyme activity

Australian consumers generally eat less bread than Europeans, with a mean intake of 32.3 kg/year for Australian adults as compared to a mean intake of 50 kg/year for European adults. Thus the margin of safety for aqualysin is >1000 fold for Australian consumers.

Aqualysin 1 does not have the characteristics of a potential food allergen and ingestion of any residual aqualysin 1 in bakery products is unlikely to pose an allergenicity concern.

Based on the toxicological data, it is concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate for aqualysin 1. A dietary exposure assessment was therefore not required.

2.2 Risk management

The risk assessment conclusions provide evidence that there are no public health and safety concerns associated with the use of this enzyme as intended. As processing aids require permissions in the Code, the main risk management option available to FSANZ is to approve or reject the request to amend the Code, and impose any conditions that may be appropriate. Other risk management issues for this Application are related to labelling and enzyme nomenclature, which are discussed below. The regulatory options analysed in section 2.4.1.1 take account of the safety of the enzyme preparation.

The Application requested an amendment to the Code to list the permission for the enzyme in section S18—4 (permitted enzymes). To do this would permit the enzyme's use for any technological purpose. The latter is not supported by the risk assessment which assessed the enzyme only for the purpose stated in the Application. For this reason, it is proposed to list the permission for the enzyme in subsection S18—9(3) and specify its use only "for use in the manufacture of bakery products".

2.2.1 Regulatory approval for enzymes

The food technology aspect of the risk assessment has concluded that the enzyme meets its stated purpose, for use as a processing aid in the manufacture of bakery products. The risk assessment has further concluded that in the absence of any identifiable hazard that an ADI of 'not specified' is appropriate for the enzyme.

Therefore, FSANZ proposes permitting the use of the enzyme as a processing aid for use in the manufacture of bakery products.

2.2.2 Enzyme and source microorganisms nomenclature

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the name "aqualysin 1" for enzymes with an EC number of 3.4.21.111 (IUBMB 2017). This is the name used in the Application and in this report.

B. subtilis is the source or host of genetically modified microorganisms for fourteen permitted enzymes in the table to subsection 18—4(5). *B. subtilis* is the host organism in this Application.

Thermus aquaticus is not currently listed in Schedule 18. The American type culture collection (ATCC) and the Deutsche Sammlung von Mikroorganismen und Zellkulturen – DSMZ (German Collection of Micro-organisms and Cell Cultures) use the name *Thermus aquaticus*. This is the name used in the Application and in this assessment summary for the donor organism.

2.2.3 Labelling considerations

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) in Standard 1.2.4 – Information requirements – statement of ingredients.

The risk assessment concludes that the use of the enzyme preparation poses no public health and safety risks. Therefore, the general exemption above will apply to the use of this enzyme preparation in foods.

2.2.3.1 Labelling requirements for food produced using gene technology

The source microorganism used to produce the enzyme is a genetically modified *B. subtilis*. However, data submitted with the Application indicates that the *B. subtilis* production strain is not detectable in the final enzyme preparation.

Labelling requirements will apply if the enzyme preparation contains novel DNA and/or novel protein which remains present in the final food (paragraph 1.5.2—4(1)(b) in Standard 1.5.2 – Food produced using gene technology). In such cases, the statement ‘genetically modified’ must be declared on the label of the food in conjunction with the name of the processing aid.

2.2.3.2 Declaration of certain substances

Wheat maltodextrin is used as a carrier for the enzyme preparation. If cereals containing gluten (including wheat) are present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid, they are required to be declared (section 1.2.3—4 in Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations).

The enzyme preparation is intended to be used to produce bakery products, which use wheat flour or other cereals containing gluten as the main ingredients. These foods will have to comply with the mandatory declaration requirement for the presence of cereals containing gluten ingredients.

2.2.4 Risk management conclusion

The risk management conclusion is to add the permission for the new enzyme aqualysin 1 sourced from *B. subtilis* containing the aqualysin 1 gene from *T. aquaticus* into the table to S18—9(3). The technological purpose is for use in the manufacture of bakery products. The maximum permitted level is GMP.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ’s standards development process. FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ’s social media tools and Food Standards News.

The process by which FSANZ considers 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 for enzymes and amending the Code to permit the use of aqualysin 1 sourced from *B. subtilis* containing the aqualysin 1 gene from *T. aquaticus* for use 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. 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:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

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, aqualysin 1 sourced from *B.subtilis* containing the aqualysin 1 gene from *T. aquaticus*, for use as a processing aid for use in the manufacture of bakery products
- (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.
Industry	The baking industry will have the opportunity to use a new enzyme which improves the machinability and development of the dough as well as improves the dough's structure. Which enzyme preparation food manufacturer's purchase and use will depend on a range of factors, including economic and performance for the proposed use.
Governments	There are no costs or benefits to governments associated with this option.

Option 2 – Reject the Application

Sector	Costs or benefits to sector
Consumers	There are no benefits or costs to consumers of this option.
Industry	There are no benefits to industry from this option, as a new enzyme will not be available that could have advantages in the baking industry.
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 outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

Schedule 18 applies in both Australia and New Zealand.

2.4.1.4 Any other relevant matters

Other relevant matters are considered 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 has undertaken a safety assessment (SD1), summarised in section 2.1 and concluded there are no public health and safety concerns with permitting the enzyme aqualysin 1 sourced from *B. subtilis* containing the aqualysin 1 gene from *T. aquaticus* as a processing aid in food.

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

The labelling approach for the processing aid is discussed in Section 2.2.3 above. This approach is consistent with the existing provisions in the Code for the labelling of permitted processing aids.

2.4.2.3 The prevention of misleading or deceptive conduct

There are 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 has 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 to assess the Application.

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

There are no Codex Alimentarius Standards for enzymes. However, this enzyme is permitted for use in Japan and China. It also meets international specifications for enzyme preparations, being the Joint FAO/WHO Expert Committee for Food Additives (JECFA) Compendium of Food Additive Specifications and the Food Chemicals Codex.

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

Permission for this enzyme preparation provides food manufacturers with an alternative enzyme, which should add to competition in supplying enzyme to the food manufacturing industries.

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

No issues were identified for this Application relevant to this objective.

- **any written policy guidelines formulated by the Forum on Food Regulation**

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

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

- 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 has determined that permitting the use of the enzyme aqualysin 1 sourced from *B. subtilis* containing the aqualysin 1 gene from *T. aquaticus* as a processing aid is consistent with the specific order 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.

4 References

Food Chemicals Codex 9th Edition (2014), The United States Pharmacopeia, United States Pharmacopeial Convention, Rockville, MD.

<http://www.usp.org/food-ingredients/food-chemicals-codex>

International Union of Biochemistry and Molecular Biology (IUBMB) Enzyme Nomenclature for EC 3.4.21.111 located at <http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/4/21/111.html> Assessed 6 April 2017

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

Attachments

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

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



Food Standards (Application A1131 – Aqualysin 1 (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 A1131 – Aqualysin 1 (Protease) as a Processing Aid (Enzyme)) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule 18 is varied by adding the following to the table to subsection S18—9(3) in alphabetical order

Aqualysin 1 (EC 3.4.21.111) sourced from <i>Bacillus subtilis</i> containing the aqualysin 1 gene from <i>Thermus aquaticus</i>	For use in the manufacture of bakery products	GMP
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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.

The Authority accepted Application A1131 which seeks to permit the use of the enzyme aqualysin 1 sourced from *Bacillus subtilis* containing the aqualysin 1 gene from *Thermus aquaticus* as a processing aid for use in the manufacture of bakery products. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The Authority has proposed that the enzyme aqualysin 1 sourced from *Bacillus subtilis* containing the aqualysin 1 gene from *Thermus aquaticus* is permitted as a processing aid for use in the manufacture of bakery products, at GMP. This requires an addition to the table to subsection S18—9(3) 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 A1131 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

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—9(3) in Schedule 18. The name of the enzyme in the table is aqualysin 1 which has the Enzyme Commission (EC) number 3.4.21.111. The source microorganism is *Bacillus subtilis* containing the aqualysin 1 gene from *Thermus aquaticus*. The technological purpose is for use in the manufacture of bakery products. The maximum permitted level is GMP.