

**2 November 2017**

**[31-17]**

Approval report – **Application A1131**

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

Food Standards Australia New Zealand (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 to manufacture bakery products.

On 20 July 2017, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation on 25 October 2017. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ’s decision on 31 October 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](http://www.foodstandards.gov.au/code/applications/Pages/A1131%20Aqualysin%201%20protease%20as%20a%20PA.aspx)[[1]](#footnote-2) which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and technical assessment report

# 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* (the Code). Aqualysin 1 (Enzyme Commission (EC) number 3.4.21.111) is sourced from *Bacillus subtilis* and contains the aqualysin 1 gene from *Thermus aquaticus*. The source microorganism is genetically modified.

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 claimed 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.

FSANZ’s risk assessment 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’ was appropriate. A dietary exposure assessment was therefore not required.

The evidence presented to support the proposed uses provided adequate assurance that the enzyme 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 FSANZ Board has approved a draft variation to permit the enzyme, aqualysin 1 (3.4.21.111) sourced from *Bacillus subtilis* containing the aqualysin 1 gene from *Thermus aquaticus* as a processing aid in the table to subsection S18—9(3) (Permitted processing aids—various technological purposes). The permitted technological purpose is for use in the manufacture of bakery products. The maximum permitted level is good manufacturing practice (GMP).

FSANZ noted 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.

Issues raised in response to a Call for Submissions report are addressed in this report.

# 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 industries, 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 process and manufacture food are considered processing aids.

Paragraph 1.1.1—10(6)(c) in the Code provides that a food for sale must not have, as an ingredient or a component, a substance that is used as a processing aid, unless expressly permitted.

Section 1.1.2—13 defines the expression ‘used as a processing aid’. That definition imposes certain requirements on substances permitted by Standard 1.3.3 and Schedule 18 to be used as a processing aid. For example, the substance must not perform a technological function in the final food for sale.

Standard 1.3.3 provides permissions for certain substances to be used as processing aids in food sold in Australia or New Zealand. The provisions of that Standard generally provide that substances listed in Schedule 18 of the Code are permitted for use as processing aids.

Permitted enzymes of microbial origin (including enzymes produced by genetically modified microorganisms) may be listed in the table to subsection S18—4(5) or the table to subsection S18—9(3), depending on whether the permission is for use for any technological purpose and/or any food, or for specific technological purposes and specific foods, respectively.

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 was assessed under the General Procedure.

# 2 Summary of the findings

## 2.1 Summary of issues raised in submissions

FSANZ sought public comments on the draft variation included in the Call for Submissions report between 20 July 2017 and 31 August 2017. Six submissions were received—three from government agencies, one from a New Zealand industry association, one from an individual consumer, and one from a consumer association.

The issues raised in submissions and FSANZ’s responses are detailed within Table 1.

Table 1: Summary of issues

| **Issue** | **Raised by** | **FSANZ response**  |
| --- | --- | --- |
| The submitter would resist any attempt to remove the following enzymes from the Code (in Schedule 8 – Food additive names and code numbers (for statement of ingredients)) and hide them as processing aids: * 1100 α-Amylase
* 1101 Proteases (papain, bromelain, ficin)
* 1102 Glucose oxidase
* 1104 Lipases
* 1105 Lysozyme.
 | Food Intolerance Network | There is no intention to remove the enzymes in Schedule 8 as part of the assessment of this Application, noting they are listed there for labelling purposes and are not permissions to use. That is well outside the scope of the assessment.With the exception of lysozyme (which, in terms of its technological purpose, is classified as a preservative (food additive)), the enzymes mentioned are permitted for use as processing aids under Schedule 18.Food additive permissions are provided in Schedules 15 and 16. Lysozyme is the only enzyme listed which is permitted as a GMP food additive in section S16—2 which, because of subsection 1.1.2—13(3), is also a processing aid. How the substance (enzyme) performs its technological purpose determines whether it is considered a food additive or processing aid. In summary, if it performs its purpose during the manufacture or processing but not in the final food, then it is considered a processing aid (see definition within section 1.1.2—13) and so does not need to be labelled. If it performs its technological purpose in the final food (as does lysozyme, in its role as a preservative) then it is considered a food additive (see section 1.1.2—11) and so needs to be labelled as per the requirements in section 1.2.4—7. As a final point, food manufacturers can add extra labelling information to that mandated by the Code; i.e. they can label for enzymes used as processing aids. |
| Concern expressed that enzymes have been classified (or are being re-classified) as processing aids and not food additives. By doing this they are exempt from food labelling and consumers are being denied this information and consumer choice. | Food Intolerance Network | The same issue was raised by this submitter for Applications A1125, A1126 and also A1130. FSANZ’s response is unchanged to that provided in the Approval Report for A1125, but is summarised here.A processing aid is defined in section 1.1.2—13 of the Code as a substance used ‘to perform a technological purpose in the course of processing [food]; and does not perform a technological purpose in a food for sale’. In general, enzymes used to manufacture food are captured by this definition and are regulated as processing aids. This has not changed; there has not been any re-classification of enzymes.FSANZ’s assessment of the Application concluded that it was appropriate to permit the triacylglycerol lipase enzyme for use in the manufacture of food as a processing aid. The issue of labelling processing aids in the statement of ingredients was considered in 1997 as part of Proposal P143 – Assessment of provisions for the statement of ingredients[[2]](#footnote-3). The exemption for processing aids was developed as a pragmatic approach taking into account the costs to the food industry of additional labelling and possible benefits to consumers. In addition, the exemption is consistent with labelling requirements internationally including within Codex Alimentarius. |
| There is some evidence of harm from enzymes that was presented to the Codex Committee on Food Additives (CCFA) in 2017 (CX/FA 17/49/12). | Food Intolerance Network | The report of the 49th Session of the CCFA (REP17/FA) (paragraph 112) that considered the document, CX/FA 17/49/12, makes no reference to information regarding amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi), and lipases (INS 1104), other than to note that the proposed deletion of these substances from Class Names and the International Numbering System (INS) for Food Additives (CAC/GL 36-1989) is outside the mandate of the working group established to consider such matters.  |
| There is recent scientific evidence of harm from genetically modified enzymes (Budnik et al. (2016))[[3]](#footnote-4). | Food Intolerance Network | FSANZ notes that the Budnik et al. paper investigates the sensitising effects of occupational exposure to enzymes used in flavour, detergent and pharmaceutical production. Occupational exposure is very different to exposure via the diet, both in terms of the route of exposure (which would generally be via inhalation and dermal exposure), and the level to which individuals may be exposed. Exposure to enzymes could be potentially high in the case of occupational handling, where the physical form of the enzyme that the individuals may be exposed to may be a purified and concentrated dust or powder, at very high levels, and on a regular basis. This is very different to what consumers would be exposed to via the diet, which is likely to be very low concentrations of the enzyme through ingestion of a blended food ingredient. In addition, residual enzyme in the final food is likely to be inactive and susceptible to digestion, like other dietary proteins. Therefore, any findings of this study are not directly relevant to consumers who might be exposed to trace levels through food. The hazard assessment conducted for this particular enzyme considered the potential allergenicity of the aqualysin 1 (in terms of ingestion) and concluded that there were no concerns (see section 2.2). The enzyme is digested (i.e. broken down to constituent amino acids) in the gastro-intestinal tract and it has no homology to known allergens. |
| Is it really necessary to keep adding more “ingredients” (including enzymes) to highly processed foods such as bakery products? The more you add the more allergies and hypersensitivities the general population can become affected by.  | Ingrid Pezzoni | FSANZ performed a risk assessment, as it does with all requests to permit new enzymes, processing aids and food additives to be added to the Code. The risk assessment is provided as SD1 and summarised in section 2.2.1 of this report. This risk assessment concluded there were no risks to public health and safety with permitting the use of the enzyme as a processing aid for the proposed purpose. The risk assessment investigated the issue of allergens and toxicity of both the enzyme preparation and the source microorganism.  |
| Though supportive of the application it wondered about the efficiency of undertaking repeated assessment of refined enzymes and whether approval of some enzymes (or source microorganisms) could be considered through FSANZ raising a Proposal. | New Zealand Food & Grocery Council | This observation and suggestion is noted but it is outside the scope of the Application. FSANZ will discuss this further with the submitter. |
| Concern that the term “bakery products” used in the draft variation referring to the use of the enzyme is not defined by the Code. The proliferation of food terms that are not defined in the Code (Standard 1.1.2) makes interpretation and enforcement difficult. | South Australia Health | This Application is not the vehicle to consider a change to the Code’s structure and use of definitions. In terms of the draft variation in issue, FSANZ does not see a need to provide a prescriptive, all-inclusive definition detailing what is and what is not a ‘bakery product’ for the purposes of this one processing aid permission. This term is already present and undefined in the Code in Schedule 15. Where definitions are provided (e.g., definition of ‘dairy products’), these definitions are only illustrative (ie, ‘dairy products’ includes …) and are not prescriptive. In the absence of a definition, these terms generally have their accepted and ordinary meaning. FSANZ is unaware of any evidence of a problem with this approach to date. Nor has any other jurisdiction raised this as an issue. |
| What is the labelling requirement if the enzyme preparation which contains maltodextrin derived from wheat as the carrier is used in the production of “gluten-free” bakery products? | South Australia Health | The presence of wheat in a food for sale will trigger a mandatory allergen declaration, irrespective of whether the wheat source is from an added ingredient, food additive or processing aid (or components of these). The onus is on the supplier to determine whether wheat is present in the final food. The conditions for making a voluntary ‘gluten-free’ claim will also apply, and include that the food must not contain detectable gluten. Refer to subsection 2.3.1.2 for further information about the declaration and claim requirements.  |

## 2.2 Risk assessment

FSANZ conducted a risk assessment on the proposed use of the enzyme. The assessment is provided at supporting document 1 (SD1) and its conclusions are summarised below.

The stated purpose of this enzyme preparation, namely, for use as a processing aid to manufacture bakery products, was clearly articulated in the Application. The evidence presented to support the proposed uses provided adequate assurance that the enzyme, in the form and prescribed amounts, was technologically justified and had 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. 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.

After undertaking a risk assessment, FSANZ concluded that there are no public health and safety issues associated with the use of the enzyme aqualysin 1 protease (EC 3.4.21.111) (aqualysin 1) from *B. subtilis*, containing a protease gene from *T. aquaticus*, as a processing aid in the manufacture of bakery products.

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 was concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) ‘not specified’ was appropriate for aqualysin 1. A dietary exposure assessment was therefore not required.

## 2.3 Risk management

The risk assessment concluded there are no public health and safety concerns associated with using this enzyme as intended. The food technology aspect of the risk assessment concluded that the enzyme meets its stated purpose, for use as a processing aid in the manufacture of bakery products, and not as a food additive. As processing aids require permissions in the Code, the main risk management option available to FSANZ was 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 consideration of costs and benefits summarised in section 5.1.1 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). Doing this would permit the enzyme’s use for any technological purpose. The latter is not consistent with the risk assessment, which assessed the enzyme only for the purpose stated in the Application. For this reason, it was decided 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”.

### 2.3.1 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 concluded 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.

#### 2.3.1.1 Labelling requirements for food produced using gene technology

The source microorganism used to produce the enzyme is a genetically modified *B. subtilis*. 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 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.

For unpackaged food, such as food displayed in an assisted service display cabinet, the mandatory ‘genetically modified’ statement must be stated in labelling that either accompanies the food or is displayed in connection with the display of the food (section 1.2.1—9 of Standard 1.2.1 – Requirements to have labels or otherwise provide information).

#### 2.3.1.2 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. Further, in the case where bakery products are made without gluten containing cereals, a ‘gluten-free’ claim can only be made subject to the food meeting the conditions set out in Schedule S4—3, for example that the food must not contain detectable gluten.

If the food is unpackaged, the allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (section 1.2.9 of Standard 1.2.1).

### 2.3.2 Enzyme and source microorganisms’ nomenclature

FSANZ noted 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 Zelkulturen – 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.

### 2.3.3 Risk management conclusion

The risk management conclusion is to add the permission for aqualysin 1 (EC 3.4.21.111) sourced from *Bacillus subtilis* containing the aqualysin 1 gene from *Thermus 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.

# 3 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal. The approved draft variation is at Attachment A.

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 was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was 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.

The Applicant, individuals and organisations that made submissions on this Application will be notified at each stage of the assessment.

# 5 FSANZ Act assessment requirements

## 5.1 Section 29

### 5.1.1 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 did undertake a limited consideration of the costs and benefits that would arise from permitting this Application.

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 manufacturers 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.

### 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 in both Australia and New Zealand. 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 has 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 had undertaken a safety assessment (SD1), summarised in section 2.2 and concluded there are no public health and safety concerns relating to permitting the enzyme preparation.

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

No issues have been identified. The labelling requirements for processing aids, genetically modified foods and allergens are discussed in section 2.3.1 – Labelling considerations.

### 5.2.3 The prevention of misleading or deceptive conduct

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

## 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 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 in assessing 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 Canada, France and the United States. It also meets international specifications for enzyme preparations, being the 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 for use in producing bakery products, which should add to competition in supplying enzymes 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](http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx)*[[4]](#footnote-5)* 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 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’.

# 6 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 Nomeclature 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. 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 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 *Bacillus subtilis* containing the aqualysin 1 gene from *Thermus aquaticus* | For use in the manufacture of bakery products | GMP |

## 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 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 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 sunsetting under the *Legislation Act 2003*.

**2. Purpose**

The Code does not currently permit the use of the enzyme aqualysin 1 sourced from *Bacillus subtilis* containing the aqualysin 1 gene from *Thermus aquaticus* as a processing aid. The purpose of this variation is to permit the use of this enzyme as a processing aid only in the manufacture of bakery products, at GMP.

**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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 20 July 2017 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 18 was 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 of the Code. 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 prescribed technological purpose is for use in the manufacture of bakery products. The maximum permitted level is GMP.

1. <http://www.foodstandards.gov.au/code/applications/Pages/A1131%20Aqualysin%201%20protease%20as%20a%20PA.aspx> [↑](#footnote-ref-2)
2. Copy available upon request to standards.management@foodstandards.gov.au. [↑](#footnote-ref-3)
3. Budnik LT, Scheer E, Burge PS, Baur X (2017) Sensitising effects of genetically modified enzymes used in flavour, fragrance, detergence and pharmaceutical production; cross-sectional study. Occupational and Environmental Medicine 74(1):39-45. [↑](#footnote-ref-4)
4. <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx> [↑](#footnote-ref-5)