

31 August 2017

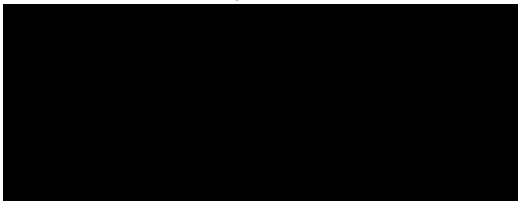
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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on ***Call for submissions – Application A1131 Aqualysin 1 (Protease) as a Processing Aid (Enzyme)***.

Yours sincerely



Katherine Rich  
**Chief Executive**



***Call for submissions – Application A1131  
Aqualysin 1 (Protease) as a Processing Aid  
(Enzyme)***

**Submission by the New Zealand Food & Grocery  
Council**

**31 August 2017**

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## NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council (“NZFGC”) welcomes the opportunity to comment on the *Call for submissions – Application A1131 Aqualysin 1 (Protease) as a Processing Aid (Enzyme)*.
2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over \$34 billion in the New Zealand domestic retail food, beverage and grocery products market, and over \$31 billion in export revenue from exports to 195 countries – some 72% of total merchandise exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 44% of total manufacturing income. Our members directly or indirectly employ more than 400,000 people – one in five of the workforce.

### THE APPLICATION

3. Puratos NV (Belgium) applied to FSANZ for permission for an enzyme, Aqualysin 1 (a protease enzyme) to be added to the *Australia New Zealand Food Standards Code* (the Food Standards Code). Proteases are used in the baking industry to hydrolyse proteins in flour to smaller peptides and amino acids and thereby change the characteristics of the dough. Puratos believes the enzyme delivers faster dough development, better machinability and improved dough structure.

### OVERARCHING COMMENTS

4. NZFGC supports the application on the basis that it is safe for consumers, use of it could deliver a better product to consumers and industry benefits from more choice in the manufacturing process.
5. We wonder about the efficiency of undertaking repeated assessments of increasingly refined enzymes and whether approval of some grouping could be considered through the raising of a Proposal by FSANZ. We know that the *B. subtilis* production strain is from a safe lineage that has been thoroughly assessed and we also know that *Thermus aquaticus* has been very commonly used in genetic research and biotechnology over the past 4 to 5 decades and that there are at least two other *Thermus* bacterium used in food from the genus of thermophilic bacteria. Perhaps these two facts could contribute to approval of a group of enzymes involving *B. subtilis* and *Thermus* bacterium for use in food in the future.

### DETAILED COMMENTS

#### ***Use of the enzyme Aqualysin 1***

6. The addition of protease Aqualysin 1 provides the following benefits:
  - faster dough development upon mixing
  - better dough machinability
  - reduced dough rigidity which results in processing tolerance
  - improved dough structure and extensibility during the shaping or moulding step
  - uniform shape of the bakery product
  - regular batter viscosity, beneficial in the production process for e.g. waffles, pancakes and biscuits
  - improved short-bite of certain products like hamburger breads.

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### **Source**

7. The host microorganism of the Aqualysin 1 enzyme is twofold. *Thermus aquaticus*, which is a thermophilic bacterium very commonly used in genetic research and biotechnology (such as for disease identification) is cloned with *Bacillus subtilis*, a genetically modified microorganism that is not pathogenic or toxigenic, and has a well-established history of use for production of enzymes used as food processing aids.

### **Current permissions Australia and New Zealand and Global**

8. There is currently no permission for Aqualysin 1 or any enzyme name with EC number 3.4.21.111 in Schedule 18 nor is there a listing for *Thermus aquaticus* in Schedule 18. However, *Bacillus subtilis* is the source of fourteen permitted enzymes in the table to subsection 18—4(5).
9. There are permissions for enzymes which have an EC number of 3.4.21.xx (a group called serine peptidases). These comprise endo-protease (EC 3.4.21.26), serine proteinase (EC 3.4.21.14) and trypsin (EC 3.4.21.4). FSANZ has also completed its assessment of Application A1121 for oryzin (EC 3.4.21.64).
10. Aqualysin 1 has been studied extensively since the 1980s, has been approved for use in food production in Canada, France and the USA and is under consideration by the EU.

### **Categorisation**

11. Aqualysin 1 is categorised as a processing aid rather than a food additive because it assists in the manufacture of bakery products but performs no function in the final food (it is inactivated during bakery manufacture).

### **Risk Assessment**

#### **Safety**

12. There is no evidence that Aqualysin 1 is genotoxic, and it was well-tolerated by rats in a repeat-dose oral gavage study. FSANZ describes the No Observed Adverse Effect level (NOAEL) in that study as being 38,400 mU2 per kg body weight(bw) per day (/kg bw/day), equivalent to 606 mg of 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.

#### **Allergenicity**

13. 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.

#### **Toxicity**

14. Based on the toxicological data, FSANZ 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.

### **Risk management**

#### **Labelling**

15. Processing aids are generally exempt from the requirement to be declared in the statement of ingredients in accordance with Standard 1.2.4 in the Food Standards Code. Since there are no public health and safety risks from Aqualysin 1, the general exemption would apply to the use of this enzyme preparation in foods.
16. Although part of the source microorganism used to produce Aqualysin 1 is a genetically modified *B. subtilis*, this is not detectable in the final enzyme preparation. Labelling requirements related to 'genetically modified' therefore do not apply.

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## **Conclusion**

17. In light of the foregoing, NZFGC supports the application on the basis that it is safe for consumers, use of it could deliver a better product to consumers and industry benefits from more choice in manufacture.
18. We wonder about the efficiency of undertaking repeated assessments of increasingly refined enzymes and whether approval of some grouping could be considered. We know that the *B. subtilis* production strain is from a safe lineage that has been tested according to the specified criteria, assessed by EFSA (2007), accorded Qualified Presumption of Safety (QPS) status by the US and that a review of the literature by the US EPA (1997) failed to reveal the production of metabolites of toxicological concern by *B. subtilis*. As set out in paragraph 8, *B. subtilis* has been assessed by FSANZ 14 times as it is the source of 14 permitted enzymes in the table to subsection 18—4(5).
19. We also know that *Thermus aquaticus* is a thermophilic bacterium very commonly used in genetic research and biotechnology over the past 4 to 5 decades and that there are at least two other *Thermus* bacterium used in food from the genus of thermophilic bacteria. Perhaps these two facts could contribute to approval of a group of enzymes involving *B. subtilis* and *Thermus* bacterium for use in food.