



**17 December 2015**

**[32–15]**

## **Administrative Assessment Report – Application A1122**

### **Thermolysin (Protease) as a Processing Aid (Enzyme)**

<b>Date received: 29 October 2015</b>		
<b>Date due for completion of administrative assessment: 19 November 2015</b>		
<b>Date completed: 13 November 2015</b>		
<b>Applicant:</b> Amano Enzyme Inc.		<b>Potentially affected Standard:</b> Schedule 18
<b>Brief description of Application:</b> To permit the use of Thermolysin (Protease) from <i>Geobacillus stearothermophilus</i> as a processing aid in the processing of proteins, yeast and flavour production.		
<b>Procedure:</b> General	<b>Estimated total hours:</b> 350  Reasons why: Seeking permission for a new enzyme	<b>Provisional estimated start work:</b> Early May 2016

#### ***Decision***

**Application accepted**

**Date: 13 November 2015**

**Has the Applicant requested confidential commercial information status?**

Yes No✓

**Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together?**

Yes No✓

***Charges***

**Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?**

Yes No✓

**Does the Applicant want to expedite consideration of this Application?**

Yes No✓ Not known

***Application Handbook requirements***

**Which Guidelines within the Part 3 of the *Application Handbook* apply to this Application?**

3.1.1, 3.3.2

**Is the checklist completed?**

Yes✓ No

**Does the Application meet the requirements of the relevant Guidelines?**

Yes✓ No

**Does the Application relate to a matter that may be developed as a food regulatory measure, or that warrants a variation of a food regulatory measure?**

Yes✓ No

**Is the Application so similar to a previous application or proposal for the development or variation of a food regulatory measure that it ought not to be accepted?**

Yes No✓

**Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?**

Yes✓ No

**If yes, indicate which Procedure:**

General

**Other Comments or Relevant Matters:**

Individual data from the sub-chronic rat toxicity study should be provided.

**Consultation & assessment timeframe**

**Proposed length of public consultation period:**

6 weeks

**Proposed timeframe for assessment:**

**'Early Bird Notification' due: 11 December 2015**

Commence assessment (clock start)	Early July 2016
Completion of assessment & preparation of draft food reg measure	Early Nov 2016
Public comment	Mid-Nov–late Dec 2016
Board to complete approval	Early March 2017
Notification to Forum	Mid-March 2017
Anticipated gazettal if no review requested	Late May 2017