

**17 December 2015**

**[32–15]**

**Administrative Assessment Report – Application A1122**

Thermolysin (Protease) as a Processing Aid (Enzyme)

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

***Decision***

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| **Application accepted**  **Date: 13 November 2015** |

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| **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***

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| **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***

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| **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***

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| **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 |