



5 October 2017
[27-17]

Administrative Assessment Report – Application A1151

β -Galactosidase from *Papiliotrema terrestris* as a Processing Aid (Enzyme)

<p>Date received: 2 August 2017 Date due for completion of administrative assessment: 23 August 2017 Date completed: 6 September 2017</p>		
<p>Applicant: Amano Enzyme Inc. Japan</p>		<p>Potentially affected standards: Standard 1.3.3, Schedule 18</p>
<p>Brief description of Application: To permit the use of β-Galactosidase derived from <i>Papiliotrema terrestris</i> AE-BLC as a processing aid in the production of galactooligosaccharide (GOS) from lactose.</p>		
<p>Procedure: General</p>	<p>Estimated total hours: Up to 350 hours</p> <p>Reasons why: Is seeking permission for a new processing aid.</p>	<p>Provisional estimated start work: Late Sept 2017</p>

Decision

Application accepted

Date: 29 September 2017

Has the Applicant requested confidential commercial information status?

Yes✓ No

What documents are affected?

Figure A-3, Table A-2, Table F-1, Table F-2, Table F-3, Table F-5

These documents are provided separately to the main Application and clearly labelled as CCI.

Has the Applicant provided justification for confidential commercial information request?

Yes✓ No N/A

Charges

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

Yes✓ No

If yes, indicate the reason:

The available evidence is that the Applicant is currently the only party that has the specific technical knowledge and expertise to produce this particular enzyme using the production strain (official name: *Papiliotrema terrestris* AE-BLC) that they have derived from the parent strain (Wild type) through a number of rounds of chemical mutation. That knowledge and expertise is not publically available – it remains proprietary to Amano Enzyme. The β -Galactosidase enzyme itself can only be made available to third parties with the permission of Amano Enzyme.

Does the Applicant want to expedite consideration of this Application?

Yes No✓

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:

Nil

Consultation & assessment timeframe

Proposed length of public consultation period:

6 weeks

Proposed timeframe for assessment:

'Early Bird Notification' due: 6 October 2017

Commence assessment (clock start)	Late-Sept 2017
Completion of assessment & preparation of draft food reg measure	Early February 2018
Public comment	Early February – mid-March 2018
Board to complete approval	Mid-June 2018
Notification to Forum	Late June 2018
Anticipated gazettal if no review requested	Early Sept 2018