

15 November 2021
178-21

Administrative Assessment Report –Application A1238

Serine endopeptidase enzyme from GM *Trichoderma reesei*

1. Application details

<p>Date received: 21 September 2021 Date due for completion of administrative assessment: 13 October 2021 Date completed: 7 October 2021</p>		
<p>Applicant: AB Enzymes GmbH</p>		<p>Potentially affected Schedule 18</p>
<p>Brief description of Application: To permit serine endopeptidase sourced from a genetically modified strain of <i>Trichoderma reesei</i> containing the serine endopeptidase gene from <i>Malbranchea cinnamomea</i>, as a processing aid in the manufacture of vegetable and animal protein hydrolysates.</p>		
<p>Procedure: General Level 1</p>	<p>Estimated total variable hours: 240 hours</p> <p>Reasons why: It will involve an assessment of relatively minor complexity, since it is assessing a new source microorganism of an already permitted enzyme</p>	<p>Estimated start date: Oct 2022 (unpaid)</p>

2. Decision

<p>Application accepted</p> <p>Date: 8 October 2021</p>

3. Additional matters

Has the Applicant requested information in the application is confidential commercial information (CCI) or confidential?

Yes CCI and confidential

What documents are affected? Appendix – CCI and Country's permissions (France and Denmark) as confidential

Has the Applicant provided redacted copies of documents containing CCI (i.e. CCI version and non CCI version and non CCI executive summary)?

Has the Applicant provided justification for why information is CCI or confidential?

Yes

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

No

4. Charges

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

No

Does the Applicant want to expedite assessment (i.e. pay) for this Application?

Yes

5. Assessment against FSANZ Act 1991 requirements

Subsection 26(2)

(b) 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

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

No

(d) Are there any other matters relevant to the decision whether to accept or reject the application?

No

Does the application meet each of the following criteria required by subsection 22(2)?

(a) The application is in writing

Yes

(b) The application is in the form specified in guideline 3.1.1 of the Application Handbook

Yes

(c) The application includes all information and each thing that the section 23 guidelines of the Act state must be included in such an application.

Yes 3.1.1 and 3.3.2

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

Yes

Indicate which Procedure:

General

Other Comments or Relevant Matters:

Nil

6. Consultation & assessment timeframe

Proposed length of public consultation periods:	
6 weeks	
Proposed timeframe for assessment	
'Early Bird Notification' due: 15 November 2021	
Commence assessment (clock start)	early Oct 2022
Completion of assessment & preparation of draft food reg measure	early Feb 2023
Public comment	mid-Feb 2023–late March 2023
Board to complete approval	mid-June 2023
Notification to Forum	late June 2023
Anticipated gazettal if no review requested	early September 2023

