

8 July 2021
161-21

Administrative Assessment Report –Application A1228

Xylanase enzyme from GM *Trichoderma reesei*

1. Application details

Date received: 19 May 2021 Date due for completion of administrative assessment: 11 June 2021 Date completed: 9 June 2021		
Applicant: Novozymes Australia Pty Ltd		Potentially affected Schedule 18:
Brief description of Application: To permit a new source microorganism, being a genetically modified <i>Trichoderma reesei</i> , for the already permitted enzyme, xylanase.		
Procedure: General	Estimated total variable hours: 240 hours Reasons why: It will involve an assessment of relatively minor complexity, since it is assessing a new GM source microorganism for an already permitted enzyme.	Estimated start date: June 2022

2. Decision

Application accepted Date: 9 June 2021

3. Additional matters

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

Yes CCI

What documents are affected?

Appendices 4.3 and 6

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

Yes

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?

No

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 No

(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

Guidelines 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: 16 July 2021

Commence assessment (clock start)	Mid-June 2022
Completion of assessment & preparation of draft food reg measure	Early Oct 2022
Public comment	Mid- Oct-late Nov 2022
Board to complete approval	Mid-March 2023
Notification to Food Ministers' Meeting	late March 2023
Anticipated gazettal if no review requested	Early June 2023

