

25 January 2022

187-22

Administrative Assessment Report – Application A1248

Glucoamylase enzyme from GM *Aspergillus niger*

1. Application details

<p>Date received: 23 November 2021 Date due for completion of administrative assessment: 14 December 2021 Date completed: 14 December 2021</p>		
<p>Applicant: Novozymes Australia Pty Ltd</p>		<p>Potentially affected standard: Schedule 18— Processing aids</p>
<p>Brief description of Application: To seek approval for a glucoamylase enzyme produced by a genetically modified strain of <i>Aspergillus niger</i> containing the gene for glucoamylase from <i>Gloeophyllum trabeum</i> as a processing aid.</p>		
<p>Procedure: General</p>	<p>Estimated total variable hours: Maximum 240 variable hours (Level 1) Reasons why: Seeking permission for a new GM microbial source for a permitted enzyme as a processing aid</p>	<p>Estimated start date: December 2022</p>

2. Decision

<p>Application accepted</p> <p>Date: 14 December 2021</p>

3. Additional matters

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

Yes

What documents are affected?

Appendix 4 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

4. Charges

The FSANZ Act provides that a charge must be imposed if the application confers an exclusive capturable commercial benefit (ECCB) on the Applicant.

Does FSANZ consider that the application confers an ECCB on the Applicant?

No

If the application does not confer an ECCB on the applicant, the FSANZ Act provides that an applicant can choose to pay a charge to expedite assessment of their application.

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 - General requirements

3.3.2 - Processing Aids

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: 27 January 2022

Commence assessment (clock start)

Mid Dec 2022

Public comment

Mid Apr – Late May 2023

Board to complete approval

Mid Sep 2023

Notification to Food Ministers' Meeting (FMM)

Late Sep 2023

Anticipated gazettal if no review requested

Late Nov 2023

