

18 May 2022
200-22

Administrative Assessment Report –Application A1252

Glucoamylase from GM *Aspergillus niger* (gene donor: *Penicillium oxalicum*) as a processing aid

1. Application details

<p>Date received: 15 March 2022 Date due for completion of administrative assessment: 05 April 2022 Date completed: 1 April 2022</p>		
<p>Applicant: Novozymes Australia Pty Ltd</p>		<p>Potentially affected standard: Schedule 18</p>
<p>Brief description of Application: To seek permission for glucoamylase from a genetically modified strain of <i>Aspergillus niger</i> containing the glucoamylase gene from <i>Penicillium oxalicum</i>, as a processing aid in baking processes, brewing processes and starch processing.</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 of an already permitted enzyme.</p>	<p>Estimated start date: April 2023</p>

2. Decision

<p>Application accepted</p> <p>Date: 1 April 2022</p>

3. Additional matters

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

Yes (CCI)

What documents are affected?

Appendix 4.3

Appendix 6

One reference

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

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?

Yes

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

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: 17 May 2022

General Procedure:

Commence assessment (clock start)

Public comment

Board to complete approval

Notification to Food Ministers' Meeting (FMM)

Anticipated gazettal if no review requested

early April 2023

early August – mid
September 2023

early January 2024

mid January 2024

end March 2024

