

1 July 2022
207-22

Administrative Assessment Report – Application A1255

Alpha-amylase from GM *Bacillus subtilis* as a processing aid

1. Application details

<p>Date received: 17 May 2022 Date due for completion of administrative assessment: 8 June 2022 Date completed:</p>		
<p>Applicant: AB Enzymes GmbH</p>		<p>Potentially affected Schedule: 18</p>
<p>Brief description of Application: To permit alpha-amylase sourced from a genetically modified strain of <i>Bacillus subtilis</i> containing the alpha-amylase gene from <i>Thermoactinomyces vulgaris</i>, as a processing aid in the manufacture of bakery products.</p>		
<p>Procedure: General</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: June 2023 (if unpaid)</p>

2. Decision

<p>Application accepted</p> <p>Date: 8 June 2022</p>
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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

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

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 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: 18 July 2022

Commence assessment (clock start)

mid-June 2023

Public comment

mid-Oct–late Nov 2023

Board to complete approval

early March 2024

Notification to Food Ministers' Meeting (FMM)

mid-March 2024

Anticipated gazettal if no review requested

early June 2024

