

13 January 2021
[146-21]

Administrative Assessment Report –Application A1218

β-Galactosidase from Bacillus subtilis (Enzyme)

1. Application details

<p>Date received: 10 Nov 2020 Date due for completion of administrative assessment: 1 Dec 2020 Date completed: 30 November 2020</p>		
<p>Applicant: Danisco New Zealand Ltd</p>		<p>Potentially affected standard: Schedule 18 to Standard 1.3.3 Processing Aids</p>
<p>Brief description of Application: To seek approval for a “β-Galactosidase (EC 3.2.1.23)” enzyme derived from a genetically modified organism for use as processing aid in dairy food applications.</p>		
<p>Procedure: General Level 1</p>	<p>Estimated total variable hours: 240</p> <p>Reasons why: It will involve an assessment of relatively minor complexity, since it is assessing a new source microorganism for an already permitted enzyme.</p>	<p>Estimated start date: January 2021</p>

2. Decision

<p>Application accepted</p> <p>Date: 30 November 2020</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?

Appendices B1, B3-B6

Appendices D1-D3

Appendix E (E1-E5)

Amino acid sequence (i.e. Appendices E4 and B4)

All toxicological studies submitted in support of this application are also considered Confidential.

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

No. CCI and confidential information is segregated from main application. Non-CCI summary is in main application and provided by the Applicant.

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

Yes

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

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: 6 Jan 2021

General:

Commence assessment (clock start)	January 2021
Completion of assessment & preparation of draft food reg measure	May 2022
Public comment	Mid May – Late June 2022
Board to complete approval	September 2022
Notification to Forum	Late September 2022
Anticipated gazettal if no review requested	December 2022