

**13 January 2021**

**[146-21]**

**Administrative Assessment Report –Application A1218**

β-Galactosidase from Bacillus subtilis (Enzyme)

1. **Application details**

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| **Date received:** 10 Nov 2020  **Date due for completion of administrative assessment:** 1 Dec 2020  **Date completed:** 30 November 2020 | | |
| **Applicant:** Danisco New Zealand Ltd | | **Potentially affected standard:**  Schedule 18 to Standard 1.3.3 Processing Aids |
| **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. | |
| **Procedure:**  General Level 1 | **Estimated total variable hours:**  240  **Reasons why:**  It will involve an assessment of relatively minor complexity, since it is assessing a new source microorganism for an already permitted enzyme. | **Estimated start date:** January 2021 |

1. **Decision**

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| **Application accepted**  **Date**: 30 November 2020 |

1. **Additional matters**

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| **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 |

1. **Charges**

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| **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 |

1. **Assessment against FSANZ Act 1991 requirements**

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| **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 |

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| **Does the application meet each of the following criteria required by subsection 22(2)?** |
| 1. **The application is in writing**   Yes |
| 1. **The application is in the form specified in guideline 3.1.1 of the Application Handbook**   Yes |
| 1. **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 |

1. **Consultation & assessment timeframe**

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| **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 |