

**5 July 2018**

**[53-18]**

**Administrative Assessment Report – Application A1167**

Lactase from a recombinant strain of Bacillus subtilis as a PA

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| **Date received: 19 June 2018**  **Date due for completion of administrative assessment:** **3 July 2018**  **Date completed: 2 July 2018** | | |
| **Applicant: DuPont Australia Pty Ltd** | | **Potentially affected standard: Standard 1.3.3, Schedule 18** |
| **Brief description of Application:**  To seek approval for the use of Lactase (β-D-galactoside galactohydrolase EC 3.2.1.23) from a recombinant strain of *Bacillus subtilis* as a processing aid in foods, specifically in dairy processing and the production of galactooligosaccharide (GOS). | |
| **Procedure:**  General | **Estimated total hours:**  350  Reasons why**:**  Seeking permission for a new GM microbial source for permitted enzyme as a processing aid. | **Provisional estimated start work:**  Early March 2019 |

***Decision***

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| **Application accepted**  **Date: 2 July 2018** |

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| **Has the Applicant requested confidential commercial information status?**  Yes ✔  What documents are affected?  Appendix B, B1, D and E  **Has the Applicant provided justification for confidential commercial information request?**  Yes ✔ |

***Charges***

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| **Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?**  No ✔ |
| **Does the Applicant want to expedite consideration of this Application?**  Yes✔ |

***Application Handbook requirements***

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| **Which Guidelines within the Part 3 of the *Application Handbook* apply to this Application?**  3.1.1, 3.3.2  **Is the checklist completed?**  Yes✔  **Does the Application meet the requirements of the relevant Guidelines?**  Yes ✔ |
| **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 ✔ |
| **Is the Application so similar to a previous application or proposal for the development or variation of a food regulatory measure that it ought not to be accepted?**  No ✔ |
| **Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?**  Yes ✔  **If yes, indicate which Procedure:**  General |
| **Other Comments or Relevant Matters:**  Nil |

***Consultation & assessment timeframe***

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| **Proposed length of public consultation period**  4-6 weeks |
| **Proposed timeframe for assessment:**  Commence assessment (clock start) Early March 2019  Completion of assessment & preparation of draft food reg measure Early July 2019  Public comment (6 weeks) Early July – mid-Aug 2019  Board to complete approval 4/5 December 2019  Notification to Forum Mid-December 2019  Anticipated gazettal if no review requested Late January 2020 |