



**5 July 2018**  
**[53-18]**

**Administrative Assessment Report – Application A1167**

Lactase from a recombinant strain of *Bacillus subtilis* as a PA

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

***Decision***

<p><b>Application accepted</b></p> <p><b>Date: 2 July 2018</b></p>
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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***

**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***

**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**

**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