

**11 September 2009**  
**[15-09]**

**APPLICATION – ADMINISTRATIVE ASSESSMENT**

A1032	<b>Date Received:</b> 29 July 2009 <b>Date Due for completion of Administrative Assessment:</b> 19 August 2009 <b>Date Administrative Assessment Completed:</b> 19 August 2009	
<b>Applicant:</b> FrieslandCampina Domo BV via Brooke-Taylor & Co Pty Ltd	<b>Potentially Affected Standard in the Code:</b>	
<b>Title:</b> $\beta$ -Galactosidase as a Processing Aid (Enzyme)  <b>Brief Description of Application:</b> To seek approval for a new microbial source for $\beta$ -Galactosidase produced from <i>Bacillus circulans</i> , for use in the production of galactooligosaccharides.	1.3.3	
<b>Procedure:</b> <b>General</b>  <b>Reasons why:</b> This processing aid is already permitted from other bacteria sources. The applicant is requesting a variation of a food regulatory measure to change the permissions for a currently used processing aid.	<b>Cost Category (General Procedure):</b> Level 1  <b>Estimated total hours (General Procedure):</b> Up to 500 hours  <b>Reasons why:</b> <ul style="list-style-type: none"> <li>• the processing aid is already permitted from other sources</li> <li>• a safety and food technology assessment is required</li> <li>• the risk management options are anticipated to be straight-forward</li> <li>• the amendment being sought is expected to have limited social and economic impact</li> <li>• it grants a permission involving a pre-market safety assessment similar to a previous assessment</li> <li>• it involves an assessment of the risk to public health and safety of average complexity</li> </ul>	<b>Estimated start work (based on payment of fees):</b> Late August 2009

**DECISION**

**Application accepted**

**Date: 19 August 2009**

**Has the Applicant claimed Confidential Commercial Information status?**

Yes ✓ No

**What documents are affected?**

**Attachment 2**

**Has the Applicant provided justification for Confidential Commercial Information status?**

Yes ✓ No

**Is the Application for a High Level Health Claim?**

Yes No ✓

**Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together e.g. a novel food and a related high level health claim.**

Yes No ✓

### ***Charges***

**Does FSANZ consider that the application is subject to ECCB?**

Yes No ✓

**Does the Applicant want to expedite consideration of this Application?**

Yes ✓ (Fees received 31 August 2009) No Not known

### ***Application Handbook Requirements***

**Which Guideline within the Part 3 of the *Application Handbook* apply to this Application:**

3.1 General requirements

3.3.2 Processing Aids

**Does the Application meet the requirements of the relevant Guideline/s?**

Yes ✓ No

**Is the checklist completed?**

Yes ✓ No

**What information is not provided?**

N/A

**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 ✓ No

**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?**

Yes No ✓

**Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?**

Yes ✓      No

**If yes, indicate which Procedure:**

**General**

**Other Comments or Relevant Matters:**

### **CONSULTATION & ASSESSMENT TIMEFRAME**

**Consultation Strategy:**

Proposed length of public consultation period:

General Procedure      (6 weeks)

**Community Involvement Category:**

**5**

Case of minor significance or complexity or with little adverse impact on individual interests

**Proposed Timeframe for Assessment (based on the stated intent of it being a paid application):**

**'Early Bird Notification' due: 7 September 2009**

General Procedure:

Commence Assessment (clock start)

31 August 2009

Completion of Assessment

Early December 2009

Public comment

Mid-December – Early February 2010

Board to complete Approval

Mid-May 2010

Notification to Ministerial Council

Late May 2010

Anticipated gazettal if no review requested

Early August 2010