

**18 August 2010**  
**[18-10]**

**APPLICATION – ADMINISTRATIVE ASSESSMENT**

A1050	<p><b>Date Received:</b> 29 June 2010  <b>Date Due for completion of Administrative Assessment:</b> 20 July 2010  <b>Date Administrative Assessment Completed:</b> 20 July 2010</p>	
<p><b>Applicant:</b> Danisco Australia Pty Ltd via Axiome Pty Ltd</p>		<p><b>Potentially Affected Standard in the Code:</b></p> <p>1.3.3</p>
<p><b>Title:</b> Acyltransferase as a Processing Aid (Enzyme)</p> <p><b>Brief Description of Application:</b> To seek approval for acyltransferase, produced from a genetically modified strain of <i>Bacillus licheniformis</i>, for use as an emulsifier.</p>		
<p><b>Procedure:</b> <b>General</b></p> <p><b>Reasons why:</b> The Applicant is requesting a variation of a food regulatory measure to permit the use of an enzyme as a processing aid. The host organism has been previously approved for production of other enzymes, however the donor organism has not been previously approved.</p>	<p><b>Estimated total hours:</b> up to 500 hours</p> <p><b>Reasons why:</b></p> <ul style="list-style-type: none"> <li>• the processing aid is currently not permitted in the Code</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 involves an assessment of the risk to public health and safety of average complexity and is expected to be similar to previous assessments.</li> </ul>	<p><b>Estimated start work:</b> (based on paid application)</p> <p>Mid-August 2010.</p>

**DECISION**

**Application accepted**

**Date:** 20 July 2010

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

Yes  No

**What documents are affected?**

Appendix E of the Application

**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

**If yes, indicate the reason:**

There are patents pending in Australia and New Zealand with respect to specific food applications and the protein sequence. These patents are likely to provide ECCB for KLM3' enzyme in Australia and New Zealand.

**If yes, indicate due date for fees to be paid** (20 business days after notification of Admin Assess made). **Note that if fees are not received by this date, the Application is automatically rejected.**

**Due date for fees: 17 August 2010 (fees received 13 August 2010)**

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

Yes  No

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

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

3.1 and 3.3.2

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

Yes  No

**Is the checklist completed?**

Yes  No

**What information is not provided?**

There are some minor omissions from the Handbook Requirements, but these do not warrant rejection..

**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**

<b>Consultation Strategy:</b> Proposed length of public consultation period: General Procedure (6 weeks)	<b>Community Involvement Category:</b>  <b>5</b> Case of minor significance or complexity or with little adverse impact on individual interests
<b>Proposed Timeframe for Assessment:</b> (based on receipt of fees by FSANZ within 20 business days of the section 27 notification)  <b>'Early Bird Notification' due: 20 August 2010</b>	
<b>General Procedure:</b> Commence Assessment (clock start) Completion of Assessment Public comment Board to complete Approval Notification to Ministerial Council Anticipated gazettal if no review requested	    13 August 2010 Mid-Nov 2010 Mid-Nov – Late Dec 2010 Early March 2011 Mid-March 2011 Late May 2011