FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

11 September 2009
[15-09]

APPLICATION – ADMINISTRATIVE ASSESSMENT

<table>
<tr><td>A1033</td><td colspan="3">Date Received: 3 August 2009
Date Due for completion of Administrative Assessment: 24 August 2009
Date Administrative Assessment Completed: 21 August 2009</td></tr>
<tr><td colspan="3">Applicant: Danisco Australia Pty Ltd via Axiome Pty Ltd</td><td>Potentially Affected Standard in the Code:

1.3.3</td></tr>
<tr><td colspan="3">Title: Maltotetrahydrolase as a Processing Aid (Enzyme)
Brief Description of Application:
To seek approval for maltotetrahydrolase, produced by fermentation using a non-toxigenic genetically modified strain of Bacillus licheniformis, to reduce the staling process of baked goods.</td></tr>
<tr><td>Procedure:
General

Reasons why:
The applicant is requesting a variation of a food regulatory measure to permit the use of an enzyme as a processing aid. This Application is not considered in either the minor or major procedure category.</td><td>Cost Category (General Procedure):
Up to 500 hours

Estimated total hours (General Procedure)

Reasons why:
• the processing aid is currently not permitted in the Code.
• a safety and food technology assessment is required
• the risk management options are anticipated to be straight forward
• the amendment being sought is expected to have limited social economic impact
• it involves a pre-market safety assessment similar to a previous assessment
• it involves an assessment of the risk to public heath and safety of average complexity</td><td>Estimated start work (based on application being paid):
Early September 2009</td></tr>
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DECISION

Application accepted **Date: 21 August 2009**

Has the Applicant claimed Confidential Commercial Information status? Yes ✓ No **What documents are affected?** Appendix E **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 7 September 2009) No Not known

Application Handbook Requirements

Which Guidelines within the Part 3 of the *Application Handbook* apply to this Application: 3.1 General requirements and 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:	**Community Involvement Category:**
Proposed length of public consultation period: General Procedure (6 weeks)	**5** Case of minor significance or complexity or with little adverse impact on individual interests

Proposed Timeframe for Assessment: (based on stated intention of paid application)

'Early Bird Notification' due: 14 September 2009

General Procedure:

Commence Assessment (clock start)	7 September 2009
Completion of Assessment	Early Dec 2009
Public comment	Mid-Dec-early Feb 2010
Board to complete Approval	Late April 2010
Notification to Ministerial Council	Early May 2010
Anticipated gazettal if no review requested	Mid-July 2010