



13 August 2008
[14-08]

APPLICATION – ADMINISTRATIVE ASSESSMENT
(Amended 18 August 2008)

A1011	Date Received: 9 July 2008 Date Due for completion of Administrative Assessment: 30 July 2008 Date Administrative Assessment Completed: 29 July 2008	
Applicant: Danisco Australia Pty Ltd via Axiome Pty Ltd		Potentially Affected Standard in the Code:
Title: Cellulase from <i>Penicillium funiculosum</i> as a processing aid Brief Description of Application: To seek approval of a Cellulase enzyme complex produced by fermentation using a non-toxicogenic strain of <i>Penicillium funiculosum</i> as a processing aid.		Standard 1.3.3
Procedure: General Reasons why: This processing aid is already permitted from other sources. The applicant is requesting a variation of a food regulatory measure to change the permissions for a currently used processing aid. This application is not considered in either the minor or major procedure category.	Cost Category (General Procedure): Up to 500 hours Estimated total hours (General Procedure): 316 Reasons why: <ul style="list-style-type: none"> • the processing aid is already permitted from other sources; • a safety and food technology assessment is required; • the risk management options are anticipated to be straight forward; • the amendment being sought are expected to have limited social and economic impact; • grants a permission involving a pre-market safety assessment similar to a previous assessment; and • involves an assessment of the risk to public health and safety of average complexity. 	Estimated start work: Mid–August 2008

DECISION

Application accepted

Date: 29 July 2008

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

Appendix E of the dossier

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 August 2008) No Not known

Application Handbook Requirements

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

3.3.2 Processing Aids

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

Yes No

Is the checklist completed?

Yes No

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: 'Early Bird Notification' due:	
<u>General Procedure:</u> (if not expedited)	
Commence Assessment (clock start)	7 August 2008
Completion of Assessment	Early December 2008
Public comment	Mid-December – mid-Feb 2009
Board to complete Approval	7 May 2009
Notification to Ministerial Council	Mid-May 2009
Anticipated gazettal if no review requested	early-August 2009