



20 November 2009
[19-09]

APPLICATION – ADMINISTRATIVE ASSESSMENT

PA1036	Date Received: 5 October 2009 Date Due for completion of Administrative Assessment: 28 October 2009 Date Administrative Assessment Completed: 19 October 2009	
Applicant: DSM Food Specialties		Potentially Affected Standard in the Code:
Title: Lipase derived from <i>Aspergillus niger</i> as a Processing Aid (Enzyme) Brief Description of Application: To approve a new microbial source for lipase produced from a genetically modified strain of <i>Aspergillus niger</i> for use in bakery applications.		Standard 1.3.3
Procedure: General Reasons why: This processing aid is already permitted from other microbial sources. The Applicant is requesting a variation of a food regulatory measure to approve a different source of a currently permitted processing aid.	Cost Category (General Procedure): Up to 500 hours Estimated total hours (General Procedure): 402 Reasons why: <ul style="list-style-type: none"> • Requires a simple safety and food technology assessment. • Expected to have limited social and economic impact. • Requires straightforward consideration of risk management options. • It involves an assessment of the risk to public health and safety of average complexity 	Estimated start work: (based on expected paid application) Late November 2009

DECISION

Application accepted

Date: 19 October 2009

Has the Applicant claimed Confidential Commercial Information status?

Yes ✓ No

What documents are affected?

Section IV 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:

Does the Applicant want to expedite consideration of this Application?

Yes ✓ (Fees received 13 November 2009) No

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:

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: 20 November 2009

General Procedure:

Commence Assessment (clock start)

13 November 2009

Completion of Assessment

Late April 2010

Public comment

Early May – Mid-June 2010

Board to complete Approval

13 August 2010

Notification to Ministerial Council

Late August 2010

Anticipated gazettal if no review requested

Early November 2010