

[3-08]
6 March 2008

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1004	Date Received: 21 January 2008 Date Due for completion of Administrative Assessment: 12 February 2008 Date Administrative Assessment Completed: 11 February 2008	
Applicant: DSM Nutritional Products		Potentially Affected Standard in the Code:
Title: Phospholipase A ₂ as a Processing Aid (Enzyme) Brief Description of Application: To seek approval for a new microbial source for phospholipase A2 produced from a genetically modified strain of <i>Aspergillus niger</i> for use as an emulsifier in bakery products, sauces and dressings.		Standard 1.3.3 – Table to clause 17 Permitted enzymes of microbial origin
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 approve a different source of a processing aid that is currently permitted.	Cost Category (General Procedure): Level 1 Up to 500 hours Estimated total hours (General Procedure): 340 Reasons why: Requires a simple toxicological, nutritional and food technology assessment. The risk management options would be straightforward as this enzyme would have a 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-March 2008

DECISION

Application accepted

Date: 11 February 2008

Has the Applicant claimed 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:

The Applicant has declared that the Application will have exclusive capturable commercial benefit for DSM Food Specialties.

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: 6 March 2008

Does the Applicant want to expedite consideration of this Application?

Not applicable as ECCB applies

Application Handbook Requirements

Which Guideline 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

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:

General Procedure:

Commence Assessment (clock start)	Mid-March 2008
Completion of Assessment	Late July 2008
Public comment	Early August to mid-September 2008
Board to complete Approval	Mid-December 2008
Notification to Ministerial Council	Late December 2008
Anticipated gazettal if no review requested	Mid-March 2009