



13 April 2010
[10-10]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1044	Date Received: 16 March 2010 Date Due for completion of Administrative Assessment: 8 April 2010 Date Administrative Assessment Completed: 7 April 2010	
Applicant: Novozymes A/S		Potentially Affected Standard in the Code:
Title: Pullulanase from <i>Bacillus subtilis</i> as a Processing Aid (Enzyme) Brief Description of Application: To permit the use of a new microbial source for pullulanase sourced from a genetically modified strain of <i>Bacillus subtilis</i> for use in the starch and alcohol industry.		Standard 1.3.3
Procedure: General Reasons why: This processing aid is already permitted from a number of other microbial sources. The Applicant is requesting a variation of a food regulatory measure to approve a new genetically modified source of a currently permitted processing aid.	Cost Category (General Procedure): Up to 500 hours Estimated total hours: (General Procedure): 422 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) Early April 2010

DECISION

Application accepted

Date: 7 April 2010

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

Section F 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 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 Guidelines?

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: 15 April 2010

General Procedure:

Commence Assessment (clock start)

8 April 2010

Completion of Assessment

Early August 2010

Public comment

Early August – Late September 2010

Board to complete Approval

Early December 2010

Notification to Ministerial Council

Mid-December 2010

Anticipated gazettal if no review requested

Late February 2011