

27 August 2019
[92-19]

Administrative Assessment Report –Application A1185

Alpha-amylase from *Aspergillus niger* as a PA (Enzyme)

Date received: 18 July 2019		
Date due for completion of administrative assessment: 8 August 2019		
Date completed:		
Applicant: Novozymes Australia Pty Ltd		Potentially affected standard: Standard 1.3.1 Schedule 18—9(3)
Brief description of Application: To permit the use of alpha-amylase sourced from a genetically modified (GM) strain of <i>Aspergillus niger</i> , expressing an alpha-amylase gene from <i>Rhizomucor pusillus</i> , as a processing aid in starch processing and the production of potable alcohol.		
Procedure: General Level 1	Estimated total hours: Maximum 240 variable hours Reasons why: Seeking permission for a new GM microbial source for a permitted enzyme as a processing aid.	Provisional estimated start work: April 2020

Decision

Application accepted
Date: 8 August 2019

<p>Has the Applicant requested confidential commercial information status?</p> <p>Yes <input checked="" type="checkbox"/> No</p> <p>What documents are affected?</p> <p>Appendix 6</p> <p>Has the Applicant provided justification for confidential commercial information request?</p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/></p>
<p>Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together?</p> <p>Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p>

Charges

<p>Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?</p> <p>Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p>
<p>Does the Applicant want to expedite consideration of this Application?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/> Not known <input checked="" type="checkbox"/></p>

Application Handbook requirements

<p>Which Guidelines within the Part 3 of the <i>Application Handbook</i> apply to this Application?</p> <p>3.1.1, 3.3.2</p> <p>Is the checklist completed?</p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p>Does the Application meet the requirements of the relevant Guidelines?</p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>
<p>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?</p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>
<p>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?</p> <p>Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p>
<p>Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?</p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, indicate which Procedure:</p> <p>General</p>
<p>Other Comments or Relevant Matters:</p> <p>Nil</p>

Consultation & assessment timeframe

<p>Proposed length of public consultation period:</p> <p>6 weeks</p>

Proposed timeframe for assessment:

Early Bird Notification' due: 12 September 2019

General Procedure

Commence assessment (clock start)	late-April 2020
Completion of assessment & preparation of draft food reg measure	late-August 2020
Public comment	early-September 2020
Board to complete approval	early-December 2020
Notification to Forum	early-January 2021
Anticipated gazettal if no review requested	mid-February 2021