



**4 October 2011**  
**[18-11]**

**APPLICATION – ADMINISTRATIVE ASSESSMENT**

<b>PA1067</b>	<b>Date Received:</b> 6 September 2011 <b>Date Due for completion of Administrative Assessment:</b> 27 September 2011 <b>Date Administrative Assessment Completed:</b> 27 September 2011	
<b>Applicant:</b> Abbott Nutrition		<b>Potentially affected Standards in the Code:</b>
<b>Title:</b> Sucromalt as a Novel Food & Alternansucrase as an Enzyme  <b>Brief Description of Application:</b> To permit the use of Xtend™ Sucromalt for use as a novel food ingredient in a range of general purpose and special purpose foods. The Application also seeks approval for the enzyme Alternansucrase.		1.5.1 – Novel foods 1.3.3 – Processing aids 1.3.4 - Identity and Purity
<b>Procedure:</b> <b>Major</b>  The Applicant requested a general procedure; however FSANZ considers that this Application requires a major procedure due to its scientific and technical complexity.	<b>Estimated total hours:</b> More than 1200 hours  <b>Reasons why:</b> The Application involves an assessment for both addition of a new novel substance to a range of foods (including infant foods, medical foods and other special purpose foods) and permission for a new enzyme processing aid derived from a microorganism.  These assessments require an extensive and complex toxicological, nutritional, food technology, and dietary modelling assessment.	<b>Estimated start work:</b> N/A

**DECISION**

<p><b>Application rejected</b></p> <p><b>Date:</b> 27 September 2011</p> <p><b>If rejected, list reasons for rejection:</b>          The Application does not meet the mandatory information requirements under subsection 22(2) of the FSANZ Act which are set out in Part 3 of the FSANZ <i>Application Handbook</i>. The Administrative Assessment does not consider the merits of the Application.</p>
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<p><b>Has the Applicant claimed Confidential Commercial Information status?</b></p> <p>Yes No ✓</p> <p><b>What documents are affected?</b> N/A</p> <p><b>Has the Applicant provided justification for Confidential Commercial Information status?</b></p> <p>N/A</p>
<p><b>Is the Application for a High Level Health Claim?</b></p> <p>N/A</p> <p><b>If so, has the Applicant made an election to have FSANZ give public notice calling for submissions under s.51 of the FSANZ Act?</b></p> <p>N/A</p>
<p><b>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.</b></p> <p>Yes No ✓</p>

***Charges***

<p><b>Does FSANZ consider that the application is subject to ECCB?</b></p> <p>Yes ✓ No</p> <p><b>If yes, indicate the reason:</b></p> <p>Sucromalt is a highly refined product obtained via proprietary manufacturing processes. On this basis, the applicant can be identified as a person or body that may derive a financial gain from the coming into effect of the draft standard that would be prepared in relation to the application.</p> <p><b><u>Due date for fees:</u> N/A</b></p>
<p><b>Does the Applicant want to expedite consideration of this Application?</b></p> <p>Yes ✓ No Not known</p>

***Application Handbook Requirements***

<p><b>Which Guidelines within the Part 3 of the <i>Application Handbook</i> apply to this Application:</b></p> <p>3.1.1, 3.3.2, 3.5.2, 3.6.2</p> <p><b>Does the Application meet the requirements of the relevant Guidelines?</b></p> <p>Yes No ✓</p> <p><b>Is the checklist completed?</b></p> <p>Yes ✓ No</p> <p><b>What information is not provided?</b></p> <ul style="list-style-type: none"> <li>Information relating to consumer awareness and potential impact on consumer understanding and behaviour</li> <li>Information to demonstrate use will not cause a nutritional imbalance in the diet</li> </ul>
<p><b>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?</b></p> <p>Yes ✓ No</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?**

Yes No

**Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?**

Yes

**If yes, indicate which Procedure:**

General

**Other Comments or Relevant Matters:**

N/A

***CONSULTATION & ASSESSMENT TIMEFRAME***

**Consultation Strategy:**

Proposed length of public consultation period:

Major Procedure post-1<sup>st</sup> Assessment (6 weeks)

Post 2<sup>nd</sup> Assessment (4 weeks)

**Community  
Involvement  
Category:**

2

Low Intensity  
Broader Focus

**Proposed Timeframe for Assessment:**

**'Early Bird Notification' due: 4 October 2011**