

29 June 2012
[14-12]

Administrative Assessment Report –Application A1072

Sucromalt as a Novel Food & Alternansucrase as an Enzyme

<p>Date received: 16 April 2012 Date due for completion of administrative assessment: 8 May 2012 Date completed: 8 May 2012</p>		
<p>Applicant: Abbott Australasia</p>		<p>Potentially affected Standards:</p> <p>1.5.1 – Novel foods 1.3.3 – Processing aids 1.3.4 - Identity and Purity 2.9.2 – Infant foods 2.9.3 - Formulated Meal Replacements and Formulated Supplementary Foods 2.9.4 - Formulated Supplementary Sports Foods</p>
<p>Brief description of Application: 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.</p>		
<p>Procedure: Major</p> <p>FSANZ considers that this Application requires a major procedure due to its scientific and technical complexity.</p>	<p>Estimated total hours: More than 1200 hours</p> <p>Reasons why: 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.</p>	<p>Estimated start work: May 2012</p>

Decision

Application accepted

Date: 8 May 2012

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

Charges

<p>Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant? Yes ✓ No</p> <p>If yes, indicate the reason: 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 a provision that would be prepared in response to the application.</p> <p>Due date for fees: 6 June 2012 Application was withdrawn on 31 May 2012</p>
<p>Does the Applicant want to expedite consideration of this Application? Yes ✓ No Not known</p>

Application Handbook requirements

<p>Which Guidelines within the Part 3 of the <i>Application Handbook</i> apply to this Application? 3.1.1, 3.3.2, 3.5.2, 3.6.2</p> <p>Is the checklist completed? Yes ✓ No</p> <p>Does the Application meet the requirements of the relevant Guidelines? Yes ✓ No</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? Yes ✓ No</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? Yes No ✓</p>
<p>Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application? Yes ✓ No</p> <p>If yes, indicate which Procedure: General</p>
<p>Other Comments or Relevant Matters: N/A</p>

Consultation & assessment timeframe

Proposed length of public consultation periods:

1st call for submissions (6 weeks)

2nd call for submissions (4 weeks)

Proposed timeframe for assessment:

'Early Bird Notification' due: N/A as withdrawn

Commence assessment (clock start)	Late May 2012
Completion of assessment	Mid-October 2012
Public comment	Mid-October – late Nov 2012
Preparation of draft food reg measure	Mid-December 2012
Public comment	Mid-December 2012 – late January 2013
Board to complete approval	Early May 2013
Notification to Forum	Mid-May 2013
Anticipated gazettal if no review requested	Late July 2013