



13 May 2011
[9-11]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1059	<p>Date Received: 29 March 2011 Date Due for completion of Administrative Assessment: 19 April 2011 Date Administrative Assessment Completed: 21 April 2011</p>	
<p>Applicant: Nutricia Australia Pty Ltd</p>		<p>Potentially Affected Standards in the Code:</p>
<p>Title: Exclusive Use of Pectin-derived Acidic Oligosaccharides</p> <p>Brief Description of Application: To approve pectin-derived acidic oligosaccharides as a novel food for exclusive use in specific brands of infant formula, and foods and supplementary foods for young children.</p>		<p>1.5.1 2.9.1 2.9.2 2.9.3</p>
<p>Procedure: Major</p> <p>Reasons why: The Applicant requested a major procedure. FSANZ agrees that this is suitable. This Application is seeking exclusive permission for a novel food ingredient requiring a pre-market approval, with no similar previous approvals. In addition the application is seeking permission to add this new substance to infant formula products, foods for infants and formulated supplementary foods for young children for the purpose of improving health outcomes.</p>	<p>Estimated total hours: 1975</p> <p>Reasons why: The Application for a novel food ingredient also requests the addition of the new substance to a range of special purpose foods for infants for the purpose of improving health outcomes. This expands the scope of the work required to complete the assessment. This involves an assessment of the risk to the health and safety of infants and young children. These target groups are highly vulnerable and infant formula is a sole source of nourishment necessitating thorough and rigorous assessment of risk. The Application will require an extensive and complex toxicological, nutritional, food technology assessment, and require targeted consultation with key stakeholders or special interest groups.</p>	<p>Estimated start work: May 2011</p>

DECISION

<p>Application accepted</p>
<p>Date: 21 April 2011</p>

<p>Has the Applicant claimed Confidential Commercial Information status?</p> <p>Yes <input checked="" type="checkbox"/> No</p> <p>What documents are affected?</p> <p>Seven of the attachments provided with the Application - Appendices 2, 3, 4, 5e, 6, 7 and Addendum 2 are affected.</p> <p>Has the Applicant provided justification for Confidential Commercial Information status?</p> <p>Yes <input checked="" type="checkbox"/> No</p>
<p>Is the Application for a High Level Health Claim?</p> <p>Yes No <input checked="" type="checkbox"/></p> <p>If so, has the Applicant made an election to have FSANZ give public notice calling for submissions under s.51 of the FSANZ Act?</p> <p>N/A</p>
<p>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.</p> <p>Yes <input checked="" type="checkbox"/> No</p> <p>Details: The Applicant is seeking exclusive permission for the use of this novel food.</p>

Charges

<p>Does FSANZ consider that the application is subject to ECCB?</p> <p>Yes <input checked="" type="checkbox"/> No</p> <p>If yes, indicate the reason:</p> <p>The Applicant is seeking exclusive permission for the use of this novel food and therefore this is will confer an Exclusive Capturable Commercial Benefit (ECCB).</p> <p>If yes, indicate due date for fees to be paid. Note that if fees are not received by this date, the Application is automatically rejected.</p> <p><u>Due date for fees: Tuesday 24 May 2011 (Fees received 6 May 2011)</u></p>
<p>Does the Applicant want to expedite consideration of this Application?</p> <p>Yes <input checked="" type="checkbox"/> No Not known</p>

Application Handbook Requirements

<p>Which Guidelines within the Part 3 of the <i>Application Handbook</i> apply to this Application:</p> <p>Sections: General requirements 3.1.1, 3.5.2 Novel Foods and 3.6.2 Special Purpose Foods</p> <p>Does the Application meet the requirements of the relevant Guideline/s?</p> <p>Yes <input checked="" type="checkbox"/> No</p> <p>Is the checklist completed?</p> <p>Yes <input checked="" type="checkbox"/> No</p> <p>What information is not provided</p> <p>N/A</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

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:

Major

Other Comments or Relevant Matters:

N/A

CONSULTATION & ASSESSMENT TIMEFRAME

Consultation Strategy:

Proposed length of public consultation periods:

Major Procedure post-1st Assessment (6 weeks)

 Post 2nd Assessment (4 weeks)

**Community
Involvement
Category:**

3

Issue requires an
intensive focussed
approach

Proposed Timeframe for Assessment:

'Early Bird Notification' due:

Commence Assessment (clock start)

6 May 2011

Completion of 1st Assessment

mid-Aug 2011

Public comment

mid-Aug – late Sept 2011

Completion of 2nd Assessment

mid-Dec 2011

Public comment

mid Dec 2011 – early Feb 2012

Board to complete Approval

early May 2012

Notification to Ministerial Council

mid-May 2012

Anticipated gazettal if no review requested

late July 2012