

23 November 2010

[23-10]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1055	Date Received: 23 September 2010 Date Due for completion of Administrative Assessment: 18 October 2010 Date Administrative Assessment Completed: 18 October 2010	
Applicant: GTC Nutrition		Potentially affected Standards in the Code:
Title: Short-chain fructo-oligosaccharides Brief Description of Application: To permit the optional addition of short-chain fructo-oligosaccharides (scFOS) to infant formula, infant foods and supplementary foods for young children as an alternative to inulin-derived substances. Also to permit the use of invertase enzyme from <i>Aspergillus niger</i> as a processing aid in the production of scFOS.		1.1.1 1.3.3 2.9.1 2.9.2 2.9.3
Procedure: General Level 4 Reasons why: This Application is seeking to permit the addition of a new substance in a limited range of special purpose foods. In addition permission to use the invertase enzyme from <i>Aspergillus niger</i> as a processing aid is included in this Application. Aspects of the assessment undertaken through a previous Proposal P306 (2008) will contribute to the assessment of this Application. The focus will be on evidence that has emerged since 2008 and one round of public consultation will be undertaken.	Estimated total hours: More than 1000 hours (1264) Reasons why: This Application for pre-market approval is requesting the addition of a new substance to a range of special purpose foods. 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. Also, the assessment of the invertase enzyme used in the production of scFOS has been included in this Application, rather than as a separate Application. This expands the scope of the work required to complete the assessment.	Estimated start work: Mid-November 2010.

DECISION

Application accepted

Date: 18 October 2010

Has the Applicant claimed Confidential Commercial Information status?

Yes ✓ No

What documents are affected?

Clinical studies referred to in the Application, and also in relation to manufacturing processes.

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 ✓

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, 3.3.2 Processing Aids, 3.6.2 Special Purpose Foods

Does the Application meet the requirements of the relevant Guideline/s?

Yes ✓ No

Is the checklist completed?

Yes ✓ No

What information is not provided?

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

<p>Consultation Strategy: General Procedure</p> <p>Proposed length of public consultation period: One public consultation round of 6 weeks</p>	<p>Community Involvement Category: 3</p> <p>Issue requires an intensive focussed approach</p>												
<p>Proposed Timeframe for Assessment:</p> <p>'Early Bird Notification' due:</p> <p><u>General Procedure:</u></p> <table border="0"> <tr> <td>Commence Assessment (clock start)</td> <td>22 November 2010</td> </tr> <tr> <td>Completion of Assessment</td> <td>Mid-March 2011</td> </tr> <tr> <td>Public comment</td> <td>Mid March – late April 2011</td> </tr> <tr> <td>Board to complete Approval</td> <td>Late July 2011</td> </tr> <tr> <td>Notification to Ministerial Council</td> <td>Early August 2011</td> </tr> <tr> <td>Anticipated gazettal if no review requested</td> <td>Mid-October 2011</td> </tr> </table>		Commence Assessment (clock start)	22 November 2010	Completion of Assessment	Mid-March 2011	Public comment	Mid March – late April 2011	Board to complete Approval	Late July 2011	Notification to Ministerial Council	Early August 2011	Anticipated gazettal if no review requested	Mid-October 2011
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