

28 July 2016
[20-16]

Administrative Assessment Report – Application A1134

Phytosterols in portion-controlled breakfast cereals

<p>Date received: 22 June 2016 Date due for completion of administrative assessment: 13 July 2016 Date completed: 13 July 2016</p>		
<p>Applicant: Sanitarium Health and Wellbeing Australia</p>		<p>Potentially affected standard: Schedule 25</p>
<p>Brief description of Application: It seeks to amend current novel food permissions for phytosterols added to breakfast cereals to allow increased concentrations for portion controlled breakfast cereals, in either individually wrapped portions or portions that can be easily divided.</p>		
<p>Procedure: General – level 3</p>	<p>Estimated total hours: Up to 1000 hours Reasons why: Application seeks a modification of existing novel food permissions, however:</p> <ul style="list-style-type: none"> • More recent data to be considered for the risk assessment, which may require further dietary exposure assessment • Applicants suggested risk management approach may not be considered suitable, alternate approach may need to be negotiated requiring stop clock and/or Section 30 letter • Possibility RIS may be required 	<p>Provisional estimated start work: When fees are received: Statutory deadline 10 Aug 2016</p>

Decision

Application accepted

Date: 13 July 2016

Has the Applicant requested confidential commercial information status?

Yes No

What documents are affected?

Attachments 3, 6, 7, 9

Has the Applicant provided justification for confidential commercial information request?

Yes No

Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together?

Yes No

Details:

Novel food exclusivity for 15 months after date of gazettal

Charges

Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?

Yes No

If yes, indicate the reason:

The Applicant has requested exclusive use of the permission, if granted, for a period of 15 months after gazettal.

Due date for fees: 10 August 2016 (fees received 25 July 2016)

Does the Applicant want to expedite consideration of this Application?

Yes No Not known

Application Handbook requirements

Which Guidelines within the Part 3 of the *Application Handbook* apply to this Application?

3.1.1, 3.5.2

Is the checklist completed?

Yes No

Does the Application meet the requirements of the relevant Guidelines?

Yes No

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 – level 1

Other Comments or Relevant Matters:

Level 3 has been considered more appropriate by FSANZ due to issues identified during the Administrative Assessment that may require additional hours. These include possible requirements for dietary exposure assessment, a regulatory impact statement, and/or further consumer behaviour assessment. The need for any of these will be confirmed on further assessment.

Consultation & assessment timeframe

Proposed length of public consultation period:

6 weeks

Proposed timeframe for assessment:

'Early Bird Notification' due: 10 August 2016

Commence assessment (clock start)	Late July 2016
Completion of assessment & preparation of draft food reg measure	Mid-Sept 2016
Public comment	Late Sept – Mid-Nov 2016
Board to complete approval	Early March 2017
Notification to Forum	Mid-March 2017
Anticipated gazettal if no review requested	Late May 2017