



9 April 2009
[5-09]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1024	Date Received: 2 March 2009 Date Due for completion of Administrative Assessment: 24 March 2009 Date Administrative Assessment Completed: 24 March 2009	
Applicant: Raisio Nutrition Ltd via Jane Barnes		Potentially Affected Standards in the Code: 1.2.3 1.3.1 1.5.1 2.4.2 2.5.1 2.5.3
Title: Equivalence of Plant Stanols, Sterols & their Fatty Acid Esters Brief Description of Application: To recognise the substantial equivalence (on safety and efficacy grounds) of plant stanols and plant sterols and their fatty acid esters (known as 'phytosterols') so that they are considered as a single chemical class of substances. To do this will ensure consistency with international regulatory permissions for 'phytosterols' and so consolidate permissions in the Code.		
Procedure: General Reasons why: The Applicant is seeking a consolidation of the current permissions for phytosterols and their esters within the Code to reflect equivalence of safety and efficacy and to reflect and incorporate the JECFA specifications into the Code.	Cost Category (General Procedure): Level 2 Up to 850 hours Reasons why: The Application will involve detailed assessments of the various phytosterols for equivalence in terms of safety, efficacy and nutritional effects. Evaluation of impact on dietary exposure required along with consideration of risk management requirements.	Estimated start work: 2nd Qtr 2009 (if paid)

DECISION

Application accepted Date: 24 March 2009

Has the Applicant claimed Confidential Commercial Information status?

Yes No ✓

What documents are affected?

Has the Applicant provided justification for Confidential Commercial Information status?

N/A

Is the Application for a High Level Health Claim?

Yes No ✓

If so, has the Applicant made an election to have FSANZ give public notice calling for submissions under s.51 of the FSANZ Act?

Not applicable

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 Not known

Application Handbook Requirements

Which Guideline within the Part 3 of the *Application Handbook* apply to this Application:

3.5.2 – Novel Foods

Does the Application meet the requirements of the relevant Guideline?

Yes ✓ No

Is the checklist completed?

Yes ✓ No

What information is not provided?

N/A

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: Proposed length of public consultation period:</p> <ul style="list-style-type: none"> • General Procedure (6 weeks) 	<p>Community Involvement Category: 3 Intensive, narrower focus</p>												
<p>Proposed Timeframe for Assessment:</p> <p>‘Early Bird Notification’ due: 24 March 09</p> <p><u>General Procedure:</u></p> <table> <tr> <td>Commence Assessment (clock start) (if paid)</td> <td>early April 2009</td> </tr> <tr> <td>Completion of Assessment</td> <td>early Aug 2009</td> </tr> <tr> <td>Public comment</td> <td>mid-Aug – late Sept 2009</td> </tr> <tr> <td>Board to complete Approval</td> <td>early Dec 2009</td> </tr> <tr> <td>Notification to Ministerial Council</td> <td>mid-Dec 2009</td> </tr> <tr> <td>Anticipated gazettal if no review requested</td> <td>late Feb 2010</td> </tr> </table>		Commence Assessment (clock start) (if paid)	early April 2009	Completion of Assessment	early Aug 2009	Public comment	mid-Aug – late Sept 2009	Board to complete Approval	early Dec 2009	Notification to Ministerial Council	mid-Dec 2009	Anticipated gazettal if no review requested	late Feb 2010
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