

**4 February 2022**  
**188-22**

## **Administrative Assessment Report –Application A1249**

Addition of phytosterols, phytostanols or their esters to plant-based milk alternatives

### **1. Application details**

<b>Date received:</b> 22 December 2021 <b>Date due for completion of administrative assessment:</b> 19 January 2022 <b>Date completed:</b> 19 January 2022		
<b>Applicant:</b> Sanitarium Health Food Company		<b>Potentially affected standard:</b> Schedule 25 - Permitted Novel foods
<b>Brief description of Application:</b> To seek approval for the addition of phytosterols, phytostanols or their esters as a novel food to plant-based milk alternatives.		
<b>Procedure:</b> General 3	<b>Estimated total variable hours:</b> 540 hours  <b>Reasons why:</b> Involves a toxicological, nutritional, food technology and dietary modelling assessment of average complexity	<b>Estimated start date:</b> February 2022

### **2. Decision**

<b>Application accepted</b>  <b>Date:</b> 19 January 2022
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### 3. Additional matters

**Has the Applicant requested information in the application is confidential commercial information (CCI) or confidential?**

Yes (CCI and confidential information)

**What documents are affected?**

Appendix 1 (Confidential)

Appendix 2 (CCI)

Appendix 4 (Confidential)

Appendix 5 (CCI)

Appendix 7 (Confidential)

Appendix 9 (CCI)

Appendix 10 (CCI)

**Has the Applicant provided redacted copies of documents containing CCI (i.e. CCI version and non CCI version and non CCI executive summary)?**

Summaries have been provided where appropriate.

**Has the Applicant provided justification for why information is CCI or confidential?**

Yes.

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

Yes

**Details:**

Exclusive use of the novel food permission for 15 months after the date of gazettal.

### 4. Charges

**The FSANZ Act provides that a charge must be imposed if the application confers an exclusive capturable commercial benefit (ECCB) on the Applicant.**

**Does FSANZ consider that the application confers an ECCB on the Applicant?**

Yes

**Reason:**

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

**Due date for fees, or if paying by instalments the first instalment of the fees 21 February 2022**

### 5. Assessment against FSANZ Act 1991 requirements

**Subsection 26(2)**

**(b) 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

**(c) Is the Application so similar to a previous application or proposal for the development or variation of a food regulatory measure that it should not be accepted?**

No

**(d) Are there any other matters relevant to the decision whether to accept or reject the application?**

No

<b>Does the application meet each of the following criteria required by subsection 22(2)?</b>
<b>(a) The application is in writing</b> Yes
<b>(b) The application is in the form specified in guideline 3.1.1 of the Application Handbook</b> Yes
<b>(c) The application includes all information and each thing that the section 23 guidelines of the Act state must be included in such an application.</b> Yes
<b>Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?</b> Yes <b>Indicate which Procedure:</b> General
<b>Other Comments or Relevant Matters:</b> Nil

## 6. Consultation & assessment timeframe

<b>Proposed length of public consultation period:</b> 6 weeks
<b>Proposed timeframe for assessment</b>
'Early Bird Notification' due: 28 February 2022
Commence assessment (clock start) <span style="float: right;">Mid-February 2022</span>
Public comment <span style="float: right;">Early July to mid-August 2022</span>
Board to complete approval <span style="float: right;">Mid-November 2022</span>
Notification to Food Ministers' Meeting (FMM) <span style="float: right;">End-November 2022</span>
Anticipated gazettal if no review requested <span style="float: right;">Mid-February 2023</span>

