

**3 June 2022**  
**204-22**

## **Administrative Assessment Report –Application A1253**

### **Bovine lactoferrin in infant formula products**

---

#### **1. Application details**

|   |   |   |
|---|---|---|
| <p><b>Date received:</b> 7 April 2022<br/> <b>Date due for completion of administrative assessment:</b> 3 May 2022<br/> <b>Date completed:</b> 3 May 2022</p>       |   |   |
| <p><b>Applicant:</b> Synlait Milk Ltd.</p>  |   | <p><b>Potentially affected standard/s:</b><br/> <i>Schedule 29—5</i> Infant formula products—substances permitted as nutritive substances<br/> <i>Standard 2.9.1-</i> Infant formula products</p> |
| <p><b>Brief description of Application:</b><br/>         To permit the voluntary use of bovine lactoferrin as a nutritive substance in infant formula products.</p> |   |   |
| <p><b>Procedure:</b><br/>         General Level 5</p>   | <p><b>Estimated total variable hours:</b><br/>         746 hours</p> <p><b>Reasons why:</b></p> <ul style="list-style-type: none"> <li>- adding a new substance to a limited range of foods</li> <li>- changing a labelling requirement for a limited range of foods</li> <li>- a complex pre-market approval.</li> </ul> | <p><b>Estimated start date:</b><br/>         May 2022</p>   |

#### **2. Decision**

|   |
|---|
| <p><b>Application accepted</b></p> <p><b>Date:</b> 3 May 2022</p> <p><b>If fees for ECCB are not received, date of rejection:</b> 1 June 2022</p> |
|---|

### 3. Additional matters

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

Yes, CCI

**What documents are affected?** Appendix 1 (all pages) and Appendix 3 (all pages)

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

**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 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:** 1 June 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

**Does the application meet each of the following criteria required by subsection 22(2)?**

**(a) The application is in writing**

Yes

**(b) The application is in the form specified in guideline 3.1.1 of the Application Handbook**

Yes

**(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.**

Yes – General requirements (3.1.1), Substances used of a nutritive purpose (3.3.3), Special purpose foods – Infant formula products (3.6.2).

**Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?**

Yes

**Indicate which Procedure:**

General

**Other Comments or Relevant Matters:**

Nil

## **6. Consultation & assessment timeframe**

**Proposed length of public consultation period:**

6 weeks

**Proposed timeframe for assessment**

'Early Bird Notification' due: 8 June 2022

General Procedure:

|  |                               |
|--|-------------------------------|
| Commence assessment (clock start)                                | Early June 2022               |
| Completion of assessment & preparation of draft food reg measure | Early September 2022          |
| Public comment (6 weeks)   | Early October - November 2022 |
| Board to complete approval                                       | Early February 2023           |
| Notification to Food Ministers' Meeting (FMM)                    | Mid-February 2023             |
| Anticipated gazettal if no review requested                      | Early April 2023              |

