

**3 June 2022**

**204-22**

**Administrative Assessment Report –Application A1253**

**Bovine lactoferrin in infant formula products**

1. **Application details**

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| **Date received:** 7 April 2022  **Date due for completion of administrative assessment:** 3 May 2022  **Date completed:** 3 May 2022 | | |
| **Applicant:** Synlait Milk Ltd. | | **Potentially affected standard/s:**  *Schedule 29—5* Infant formula products—substances permitted as nutritive substances  *Standard 2.9.1*- Infant formula products |
| **Brief description of Application:**  To permit the voluntary use of bovine lactoferrin as a nutritive substance in infant formula products. | |
| **Procedure:**  General Level 5 | **Estimated total variable hours:**  746 hours  **Reasons why:**   * adding a new substance to a limited range of foods * changing a labelling requirement for a limited range of foods * a complex pre-market approval. | **Estimated start date:** May 2022 |

1. **Decision**

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| **Application accepted**  **Date**: 3 May 2022  **If fees for ECCB are not received, date of rejection:** 1 June 2022 |

1. **Additional matters**

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| **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. |

1. **Charges**

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| **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 |

1. **Assessment against FSANZ Act 1991 requirements**

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| **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 |

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| **Does the application meet each of the following criteria required by subsection 22(2)?** |
| 1. **The application is in writing**   Yes |
| 1. **The application is in the form specified in guideline 3.1.1 of the Application Handbook**   Yes |
| 1. **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 |

1. **Consultation & assessment timeframe**

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| **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 |