

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