



10 November 2022

To Whom It May Concern,

Tatua Submission on Application A1253 Application 1253 – Use of Bovine Lactoferrin in Infant Formula Products

Thank you for the opportunity to provide feedback on Application A1253 to amend the Australia New Zealand Food Standards Code permitting the use of bovine lactoferrin in the manufacture of infant formula.

Firstly, Tatua supports the amendment. Lactoferrin has been used for many years as an ingredient both in infant formula and other food products in countries around the world, with no reported safety concerns. Independent studies further confirm its safety for use.

However, while we support the amendment and acknowledge the need to ensure that any material used in products consumed by such a vulnerable population is safe, we are concerned that the draft specification is overly prescriptive, appears to include parameters which are not essential to the safety of the product, and is not aligned with standards in other markets. As such it will impose an unnecessary regulatory burden on manufacturers.

The proposed specification and limits appear to reflect the applicant's product specification as opposed to being based on food safety risk. We are particularly concerned that the proposed maximum iron limit of 15mg/100g will unnecessarily preclude lactoferrin manufactured using existing technologies and is not aligned with EU and China standards, as shown overleaf in Table One.

Parameters such as fat, aflatoxin and melamine also appear to be based on the applicant's product specification rather than based on risk. Limits for contaminants, while achievable, seem unnecessarily tight when compared to other global standards and considering the usage rate being proposed.

Lastly, it is proposed that testing of pH be carried out on a 10% solution as opposed to the 2% required in both the China and EU standards. There is no justification for this, resulting in additional (and unnecessary) testing.

As such we submit that the lactoferrin specification, including both parameters and limits, should more closely align with the Chinese and EU standards i.e. that:

- the maximum iron level should be increased from 15 to 35mg/100g
- parameters such as fat, aflatoxin, melamine, nitrate and nitrite are removed
- pH be tested at 2% solids

[REDACTED]



Table One: Comparison of Proposed FSANZ Specification Against Other Market Regulatory Limits

Parameter	Proposed FSANZ Specification	China Standard (GB1903.17-2016)	EU Standard (2012/725/EU)
Protein (N x 6.38)	> 95.0%	> 93.0%	> 93.0%
LF Purity (% of protein)	> 95.0%	> 95.0%	> 95.0%
Moisture	< 4.5 g/100g	≤ 4.5%	< 4.5%
Ash	≤ 1.3 g/100g	≤ 2.0%	<1.5%
Iron	≤ 15 mg/100g	≤ 35 mg/100g	< 35 mg/100g
Fat	≤1 g/100g		
pH	5.2 – 7.2 (10% solution)	5.2 – 7.2 (2% solution)	5.2 – 7.2 (2% solution)
Solubility (2% solution)	Transparent	Complete, transparent	Complete
Arsenic	≤ 0.02 mg/kg	≤ 1.0mg/kg	< 2 mg/kg
Cadmium	≤ 0.1 mg/kg		
Lead	≤ 0.02 mg/kg	≤ 1.0 mg/kg	
Mercury	≤ 0.1 mg/kg		
Nitrate	≤ 50.0 mg/kg		
Nitrite	≤ 2.0 mg/kg		
Aflatoxin	≤ 0.05 ug/kg		
Melamine	Not Detected		
Aerobic Plate Count		≤ 1000 cfu/g	
Coag. Positive Staphylococci		Not Detected/25g	
Coliforms		< 3.0 MPN/g	
Cronobacter species	Not Detected/300g		
Listeria	Abs/25g		
Salmonella	Not Detected/250g	Not Detected/25g	
Yeasts & Moulds		≤ 10 cfu/g	

Thank you again for the opportunity to comment.

Yours sincerely,

