



10 November 2022

Standards Liaison Officer  
Food Standards Australia New Zealand

By email: [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au)

**A1253 – Bovine Lactoferrin in Infant Formula Products [6 October 2022, 216-22]**

On 6 October 2022, Food Standards Australia New Zealand called for submissions in relation to Application A1253 - Bovine Lactoferrin in Infant Formula Products.

The a2 Milk Company Ltd and its related companies (together, a2MC) has had the opportunity to contribute to and review the submission of the Infant Nutrition Council (INC) on this Application.

a2MC supports the position taken by and comments made in the INC submission.

a2MC wishes to comment on certain aspects of the call for submissions paper - our responses are provided in **Attachment 1** to this letter.

Please do not hesitate to contact me if you have any questions in relation to this submission.

Yours sincerely

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## ATTACHMENT 1: a2MC specific responses to A1253

### *Support for voluntary addition of bLf to infant formula products*

a2MC strongly supports the voluntary addition of bLf to infant formula products up to a maximum of 40mg/100kJ (equivalent to around 1109mg/L) and supports the amendment of Standard 2.9.1 of the Australia New Zealand Food Standards Code for this purpose.

### *bLf as a 'nutritive substance'*

a2MC notes that bLf has been proposed as a nutritive substance or addition to infant formula products at levels up to 40mg/100kJ.

a2MC considers the classification of nutritive substances (and novel foods) appears open to interpretation in the absence of completion of P1024 to provide industry and stakeholders regulatory clarity.

If FSANZ deems bLf to be a nutritive substance, there will be an impact on the general food industry as it will mean that bLf (in isolated form) is not permitted to be added to other food categories **and** being used for the same purpose in any other unapproved food of food category.

The implication of this is that manufacturers will be required to lodge an application to FSANZ for approval, for every additional food they wish to add lactoferrin to as an ingredient. Additionally, there will be significant cost and administrative burden of this outcome, especially for those manufacturers who currently have bLf-containing food products on the market. Their products will be in breach of the Code and will require withdrawal from the market, and potentially reformulation and re-labelling.

a2MC seeks clarification from FSANZ that the Code does not prevent the same food or substance being added for more than one purpose, whether these are purposes requiring premarket approval or are un-regulated.

a2MC recommends that, following conclusion of this Application (A1253), FSANZ convenes a workshop of stakeholders to discuss the future application/use of the term 'nutritive substance'. The outcomes of such a workshop could contribute to production of guidance for stakeholders.

### *Specification*

The proposed standard is very specific and not risk-based or proportionate. It imposes a regulatory burden where the risk is not clear (especially for the extent of parameters).

a2MC proposes the following alternate option for consideration:

1. In the absence of an EU or China specification for a parameter, the proposed standard for the Australia New Zealand Food Standards Code should not be included.

This would omit parameters for fat, solubility, cadmium, mercury, aflatoxin, melamine, aluminium, nitrate, and nitrite.

2. Where parameters are in place in the EU or China then these limits should be adopted.
3. Where parameters are in place in the EU and China, then the more stringent should be adopted.



- Specifically, we recommend that the iron content is amended to  $< 35 \text{ mg/100g}$  to align with EU and China regulatory limits.

#### *Exclusivity*

a2MC is supportive of the concept of exclusive capturable commercial benefit and fully recognises the value this has to encourage investment in innovation in the food industry.

