



Dr Sandra Cuthbert  
Chief Executive Officer  
Food Standards Australia New Zealand  
Level 4, 15 Lancaster Place  
Majura ACT 2609

Re: A1253 - Bovine lactoferrin in infant formula products Call for Submissions

Dear Dr Cuthbert

Please accept this as our submission to the Call for Submissions on Application A1253 – Bovine lactoferrin in infant formula products issued 6 October 2022 ('Application').

We welcome the opportunity to provide comment and raise our concerns in reference to the application A1253 and more broadly as to the regulatory framework.

### **Lactoferrin is a milk solid first**

In 1.3.1.1 of the Call for Submissions ('CFS') identifies that as the draft variation seeks to insert lactoferrin into Schedule 3, then lactoferrin is proposed to be used as a nutritive substance. This implies that where the variation did not seek to vary Schedule 3 but instead modified Standard 2.9.1, it would not be a nutritive substance. The CFS continues in 1.3.1.2 to resolve that on the basis that it is to be used as a nutritive substance then its express permission is required. This results in the intent for its inclusion as the definitive basis for an ingredient to be a nutritive substance.

The definition of nutritive substance as outlined in 1.3.1.5 of the CFS clarifies that if the ingredient is added for a 'nutritional purpose' that has been concentrated, refined or synthesised with 1.3.1.3 noting that Standard 2.9.1 identifies the inclusive list of such substances. However, while Section 29-5 does not list lactoferrin, it also doesn't list any other milk solid, nor tryptophan, nor high-oleic sunflower oil, all of which are concentrated and refined ingredients.

Compliance with the rest of Standard 2.9.1 requires the use of a protein source, and Schedule 29-6 defines minimum amino acid levels that Standard 2.9.1-10 (2) then permits to be added to achieve compliance and to improve protein quality. The ingredients are being added to achieve this compliance are by definition added for a nutritional purpose, yet they are not in Schedule 29-5 and their use has not required premarket assessment via an application to Food Standards.



Section 2.2.2 of the CFS notes that lactoferrin is part of bovine milk. Lactoferrin is by implication part of our food supply and is within the milk solids concentrated and refined from milk used in food, including in the manufacture of infant formula in order to comply with Standard 2.9.1.

### **Inappropriate consideration of exclusivity**

In 2.2.10 of the CFS it is stated that exclusive use may be applied for to recognise the investment made *by the applicant* in developing a nutritive substance and the need to return on this investment. This is an important concept to support the development and innovation in foods for the wellbeing of the community and a principal we endorse.

Lactoferrin as a concentration of a part of the solids of bovine milk is a commonly available milk solid product of multiple traditional milk processing companies within at least Europe, the United States, New Zealand and Australia. The applicant may have undertaken some development of lactoferrin, but this is incidental as it remains available via multiple sources of supply without their action. The inclusion of lactoferrin as a shelf-stable milk solid is like any other milk solid used in manufacture of infant formulas to provide the protein, fat and carbohydrates and as such does not promote the need for innovation or investment.

It does not seem appropriate to obtain a monopoly on an ingredient solely arising from the effort to make the application itself. It would appear perverse for this application to provide the precedent to enable the ability for an applicant to seek a monopoly on whey protein concentrates where they are nominated to be added as a nutritive substance rather than a milk solid.

In the strongest possible terms, we object to the proposed approach to grant a monopoly on the use of lactoferrin or any commonly available derivative of milk in infant formula or other foods.

### **Confusing consumer messaging**

A cursory search online for lactoferrin or a walk down the baby aisle at the supermarket will identify lactoferrin products targeted for use by infants that are packaged and branded as consumers would expect to see infant formulas along with products packaged and branded as consumers would expect to see vitamin style supplements.

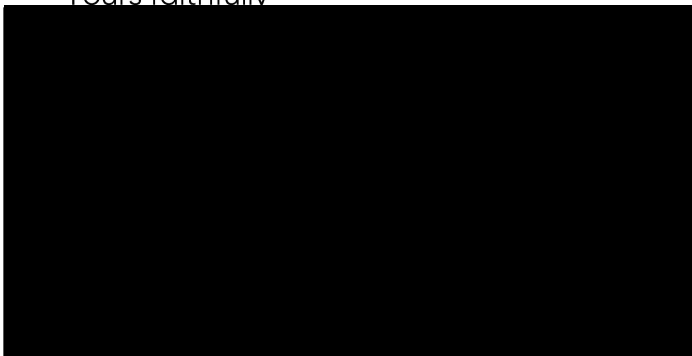
In a regulatory sense, each of these products is likely to be under the oversight of the Therapeutic Goods Administration and not considered as a food. However, this delineation between a milk-based food and a milk-based therapeutic good is not obvious to consumers.

The noted controls on infant formula labelling in 2.2.8 of the CFS and more broadly the near prohibition on the capacity to express genuine therapeutic benefits of foods means that many consumers are likely to be adding to their weekly shopping costs solely due to regulatory constraints on what would be accurate consumer communication.

There is considerable innovation occurring in food across the planet and a broad acceptance of its role in health and wellness. That is, the acceptance that food is fundamentally therapeutic. The consideration of lactoferrin as a nutritive substance and at levels above its use as a milk solid is to acknowledge the scientific evidence of its benefits for infant development in the Food Standard. However, the variation to the Food Standard as proposed does so in a manner to mean that the benefit cannot be communicated to the consumer. This does not appear to be in the interests of the life-long health of the community.

We continue to support FSANZ in its role and its governance of the Code to support improved health and wellness in the community. Please feel free to contact me regarding any clarifications sought on this submission.

Yours faithfully



#### About Care A2 Plus

Care A2 Plus Pty Ltd ('Care A2+') is an Australian health and wellness food manufacturer based in Sydney with a manufacturing facility in Mulgrave, Victoria. Care A2+ was founded in 2018 and launched its first range of products, being Infant Formulas and a Toddler Formula in October 2020.

A key point of difference of Care A2+ is its control and management of the product from Grass-to-Tin® where from purchasing and processing the milk, Care A2+ establishes the specifications for each interim ingredient and product that combined becomes the finished product. This approach affords Care A2+ the capacity to incorporate innovation into the process and finished product along with flexibility to respond to the requirements of our various export markets regulations and consumer preferences.

