Synlait

To
Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA

Dunsandel, 10 November 2022

Synlait Milk Ltd. (Synlait) Response to Call for submissions – Application A1253 ***Bovine lactoferrin in infant formula products***

Dear Sir/Madam,

As the applicant of Application 1253, Synlait thanks FSANZ for preparing the consultation papers and the opportunity to comment on FSANZ's conclusions based on our submission.

Synlait believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breast milk the only suitable and safe alternative is a scientifically developed infant formula product. For these products to be safe for infants, there is a need for the Australia New Zealand Food Standards Code (the Code) to ensure that infant formula products (IFP) on the market in Australia and New Zealand protect the health and safety of formula-fed infants, which Synlait fully supports.

As a Member of the Infant Nutrition Council (INC), Synlait also provides its support for the views expressed in the INC Submission, having participated in the preparation of that submission.

Synlait thanks FSANZ for consideration of our feedback. If you have any questions, please do not hesitate to contact us.

Synlait

General comments

Synlait supports FSANZ's proposed amendments to the Food Standards Code.

Nutritive substance

Synlait agrees with FSANZ's conclusion that bovine lactoferrin (bLf) is a nutritive substance for the following reasons:

- Intended purpose: the intended purpose of adding bLf to infant formula products is to provide a nutritional purpose, i.e. to provide a physiological health benefit (reduced risk of infection), similar to other nutritive substances (e.g. 2'- fucosyllactose, lutein, inositol, choline).
- Amount added: the proposed maximum addition rate to infant formula products is significantly higher than what is naturally contributed by dairy ingredients, i.e. bLf will be present in a concentrated form (up to 40mg/100kJ, which equals to around 1109mg/L[1] vs. 10-27mg/L in unfortified formula[2]).
- Form of added bLf: the proposed addition of bLf to infant formula products is as an isolated, concentrated ingredient rather than a dairy ingredient that naturally contains bLf.
- bLf is recovered from milk using ion exchange technology and is then pasteurised, filtered, concentrated and spray-dried in a manner that minimises denaturation and thereby protects its bioactivity (incl. antibacterial, antiviral, immunomodulatory effect), ensuring delivery of bLf's health benefit (reduced risk of infection).

It is clear that the addition of bLf at levels up to 40mg/100kJ meets the Food Standards Code definition of 'used as a nutritive substance". The view that bLf is a 'food', and therefore express permission is not required to add it to IFP simply because it is naturally present in milk, is not valid. Interpretative Advice issued by MPI Food Science in July 2012 clearly sets out the reasons for this (refer Attachment A). Notably, if that logic was true there would be no need for the specific permissions for the addition of several other milk constituents such as calcium, choline and other vitamins and minerals.

Maximum addition levels

Synlait supports the proposed maximum addition levels of bLf of 40mg/100kJ (equalling around 1109mg/L), which is close to average bLf content of mature human milk of Australian women (around 1230-1420 mg/L), and is consistent with maximum permitted levels in the European Union and other countries (e.g. China). We strongly support international harmonisation, and we note that consistency between domestic and international food standards and an internationally competitive food industry are two Ministerial High Order Policy Principles FSANZ must have regard to when developing new regulatory measures. Permitting the addition of bLf to IFP at levels up to 40mg/100kJ will enable New Zealand and Australian infant formula manufacturers to be competitive in an internationally aligned environment.

Evidence supporting benefit

Synlait agrees with FSANZ's conclusion that there is strong evidence from *in vitro* and animal studies supporting bLf's benefit of reduced risk of infection. We believe that there is good evidence from human studies supporting

[1] Supporting document 1, Table 3

[2] Pang, J., Xiao, Q., Yan, H., *et al.* (2020). Bovine lactoferrin quantification in dairy products by a simple immunoaffinity magnetic purification method coupled with high-performance liquid chromatography with fluorescence detection. J Agric Food Chem, 68(3), 892-898.

the benefit of bLf, even at levels lower than what is typically found in breast milk. Consistent with Ministerial Guidelines, there is a clear link between the physiological, biochemical and functional effects of bLf to a specific health outcome for infants.

It is worth noting that any lactoferrin contributed to infant formula from ingredients such as milk and whey protein concentrates is almost entirely denatured during manufacture of infant formula base powder, which impacts the bioactivity of bLf. Therefore, adding bLf at dry-blend stage, even at relatively low levels, is the best way to ensure bLf provides a health benefit, compared to non-fortified IFP. (It is also worth noting that in the study by King *et al.* 2007, the "naturally occurring" bLf in the 'low-bLf' formula is most likely entirely denatured, which is important context when interpreting the findings.)

Specification

Synlait is open to supporting widening of the specification where alignment with international standards is appropriate, in particular with the EU and China, provided that exclusivity of 15 months is granted for Synlait bLf. This is to ensure that Synlait is able to achieve an appropriate return on investment, since widening of the specification will enable other manufacturers to use Synlait's paid application for their bLf.

If the specification is aligned with international regulations, we strongly encourage alignment with the stricter standards where they diverge between the EU, China and/or other countries. We strongly oppose widening of specifications beyond those set by the EU and/or China, in particular for purity of bLf (i.e. %bLf on a protein basis), total protein content and iron content. We believe this is important to ensure access to both the EU and China markets and allow New Zealand and Australian manufacturers to remain internationally competitive. Furthermore, this approach is in line with the principle of minimum effective regulation and does not create any technical barriers to trade.

The addition of bLf is aligned with the 'High Order' Policy Principles of the protection of public health and safety, informed consumer choice and the prevention of misleading or deceptive conduct. The permission to add bLf to Infant formula products will promote consistency between domestic and international food standards and will help promote an efficient and internationally competitive food industry.

Exclusivity

We support FSANZ's recommendation that Synlait should be granted 15 months exclusivity. Synlait has made significant investment in the development of an infant-grade bLf, in writing the application, and is paying for the fee to cover the assessment of the application in full. As noted above, Synlait is open to widening the specifications, which means that other companies can benefit from the application once the exclusivity period is over. Not granting an exclusivity period means we will not get appropriate return on investment. This will erode the incentive for Synlait and other companies to do future applications, as they will not have a competitive advantage and not get appropriate return on investment. This may hinder innovation going forward.

Exclusive permissions for nutritive substances were introduced by FSANZ and endorsed by the Food Ministers Meeting in November 2020 as part of the assessment and approval of Application A1155. Synlait's application is not the first nutritive substance application to be granted exclusivity.

Comments on specific sections in the documents

Call for Submissions

Attachment A, S-3-46 Specification for bovine lactoferrin: There is a typo in the specification for iron content – it should be "not more than 15**mg**/100g)"

Synlait

Supporting Document 1

Executive summary, second to last paragraph: FSANZ noted that one of the included RCTs investigating the effect of bLf on risk of infection also investigated the effect of bLf on iron status. It is worth noting that several other RCTs investigated the effect of bLf on iron status showed that bLf does not negatively impact iron status and may in fact support a healthy iron status; these studies are outlined in section 3.2.1.2 of the Application.

Section 2.2.3, first paragraph:

- Please note that bLf may also be used in liquid IFP or liquid concentrate.
- The last word should be “bioactivity” rather than “bioavailability”.

Section 2.2.6: We note that FSANZ mentions a benefit on microbiota in this paragraph, which is not the benefit of bLf proposed in the application.

Section 4.4 (*The effect of bovine versus human lactoferrin on nutrient* ***bioavailability***): The evidence presented focuses on comparing iron status parameters of formula-fed infants consuming bLf-fortified IFP with those of human milk-fed infants. Synlait is of the view that this comparison does not allow drawing conclusions on the effect of hLf and bLf on iron *bioavailability,* especially because iron levels in human milk are low while IFP products are generally fortified with iron. We believe that a more appropriate way of assessing the impact of bLf on nutrient *bioavailability*, and consequently the effect on iron status, may be by evaluating studies that compare bLf-fortified formula with the same formula that is not fortified with bLf in formula-fed infants. We presented several studies in our application, of which all show that bLf-fortification of formula does not negatively affect nutrient bioavailability and may in fact support iron absorption and iron homeostasis (see section 3.2.1.2 of the Application).