A1253 - Call for submissions
Bovine lactoferrin in infant formula products

Submission by Public Health Services, Department of Health, Tasmania

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Thank you for the opportunity to comment on the call for submissions for Application *A1253 - Bovine lactoferrin in infant formula products.*

Application A1253 seeks to permit the voluntary addition of bovine lactoferrin (bLF) to infant formula, follow-on formula and infant formula for special dietary use up to a maximum of 40mg/100kJ.

Public Health Services, Tasmania has the following comments on this application.

FSANZ assessment of the beneficial effect of the addition of bLF to infant formula suggests a plausible mechanism based on *in vitro* studies and animal studies. FSANZ also acknowledges the evidence in human studies of full-term infants is limited, of low quality and does not provide obvious links to the mechanistic evidence from these *in vitro* studies. Chen et al. (2016) study did show a reduction in respiratory infections with the addition of bLF but Bjormsjo et al. (2022) did not show any difference and in fact this study was more focussed on the comparison of low iron formula +/- b LF than the addition of bLF alone and concluded that bLF does not affect iron status.

The *Ministerial Policy Guideline on the Regulation of Infant Formula Products* states

> *j) Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a* ***substantiated beneficial role in the normal growth and development of infants or children****, or a technological role, taking into account, where relevant, the levels of comparable substances in breastmilk. A substance's role in normal growth and* ***development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood****.*

Public Health Services does not consider 'plausible' evidence that bLF has an anti-bacterial, anti-viral or immunomodulatory effect function to be an appropriate level of evidence given the vulnerability of this population group, where formula for some infants may be the sole or principle source of nutrition.

As raised in previous submissions Public Health Services is concerned with precedence setting for future applications if this application is accepted based on 'plausible' mechanisms and low-quality human studies. As stated in the FSANZ paper the first bLF infant formula products were released for sale overseas in 1986, yet over 30 years later we do not have any good quality studies in infants of the beneficial role of bLF in these products. Whilst there is no evidence of adverse events from the addition of bLF there is also limited evidence of a beneficial role. It is possible that optional ingredients such as bLF may in fact increase risk to infants more broadly by creating a marketing advantage, contributing to misinformation and leading to unnecessary use of infant formula. Research has found that infant formula with optional ingredients are positioned as close to, equivalent and sometimes superior to breast milk often with scientific evidence that does not support the validity of these claims. This may undermine efforts to support breastfeeding and is a potential risk to infants (Munblit et al., 2020).

Public Health Services recommends that FSANZ consider a similar process for review of the evidence that has been put in place for A1155 (addition of 2 FL to infant formula products). This was agreed by the Food Ministers Meeting (previously the Australian and New Zealand Ministerial Forum on Food Regulation) on 27 November 2020 based on weak evidence of beneficial role in normal growth and development.

This approach is further supported by Public Health Services submission for P1028 (June 2022) where we recommended that a mechanism to review the evidence of optional ingredients after a specific timeframe (eg. 5 years after gazettal) is included in the revised standard to ensure nutritive substances such as bLF are either added to all infant formula or revoked. Whilst Public Health Services understands that optional ingredients have been permitted in the Code to enable industry to innovate and improve outcomes for formula-fed infants, remaining optional with no process of review is not in line with protecting the health and safety of all infants. If substances have a substantiated beneficial role in normal growth and development by keeping them optional many infants are missing out on key nutrients. Alternatively, there may be consumers purchasing infant formula (often at a premium price) because it contains an optional ingredient that may not have a substantiated beneficial role in growth and development placing a greater strain on family's budgets.

Public Health Services notes that the Office of Best Practice Regulation (OBPR) granted FSANZ exemption from the requirement to develop a Regulatory Impact Statement for Applications relating to the voluntary addition of nutritive substances to foods. FSANZ however have given consideration to the costs and benefits that may arise from the addition of bLF to infant formula products. Public Health Services does not support the benefit for consumers outlined by FSANZ '*consumers would potentially benefit from an increase in choice of IFP in the market*'. Increasing choice is a speculative benefit and may in fact increase consumer confusion on what formula to choose. If there was strong evidence for the role of bLF in infant formula products, then the benefit to consumers is a reduction in bacterial

and viral respiratory infections. The benefits outlined by FSANZ are very much focussed on Industry sales in international markets, not the growth and development needs of this vulnerable population group.

References

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