Comments from the Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions.

Due date of submission – 10 November 2022

The Victorian Departments of Health and Jobs, Precincts and Regions (the departments) welcome the opportunity to respond to this application to amend the Australia New Zealand Food Standards Code (the Code).

Application A1253 – Bovine lactoferrin in infant formula products (the Application) seeks to permit the voluntary addition of bovine lactoferrin (bLf) as a nutritive substance to infant formula products.

From the Food Standards Australia New Zealand (FSANZ) Assessment report and supporting document, it is understood that:

- Lactoferrin is an iron-binding protein naturally present in mammalian milks, including human and cow (bovine) milk. Chemical structure differs between sources, and bLf has two additional potential glycosylation sites compared to human lactoferrin (hLf).
- The proposed bLf is extracted from cow milk and concentrated through several processes, including ion exchange and ultrafiltration.
- The Applicant has stated the purpose of adding bLf to infant formula is to more closely reflect the lactoferrin content in human milk, and to reduce the risk of infection in infants fed formula not supplemented with bLf.
- FSANZ's risk and technical assessment found that there are no public health and safety concerns with the addition of bLf to infant formula products at the proposed level.
- FSANZ also assessed evidence of a beneficial health outcome in infants as required by the relevant policy guideline. The assessment concluded that in vitro and animal studies, and a small number of human intervention trials support a plausible mechanism by which bLf can reduce the risk of bacterial and viral infection.
- Based on these assessments, increased compositional alignment with human milk, and consistency with international regulations, FSANZ proposes to permit bLf as a nutritive substance in infant formula products up to a maximum permitted amount of 40mg/100kJ.

Summary of key views

The departments:

- support progression of the Application conditional on a periodic review of evidence of the substantiated health benefit.
- request clarification on the scope of the proposed exclusive permission.
- request consideration of the impact of exclusivity on infant health and safety under FSANZ's higher order principles.

Evidence of substantiated health benefit

The departments acknowledge bLf has a history of safe use in infants and has been available in infant formula overseas since 1986 with no known reported adverse effects. We also note that bLf is permitted in infant formula at a maximum of 1000mg/L prepared formula in Singapore, China and the European Union, which is approximately equivalent to the 40mg/100kJ proposed in Application A1253. However, recognising infant metabolism is immature, the Ministerial Policy Guideline on the Regulation of Infant Formula Products requires that substances added to infant formula should not only be safe, but also have a substantiated beneficial role in the normal growth and development of infants. The policy guideline states "A substance's role in normal growth and development is substantiated where there is appropriate evidence to link physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear."

While in vitro and animal studies presented by FSANZ provide evidence of a plausible health benefit of bLf in infants, we do not believe they are sufficient to substantiate the relationship. The departments consider evidence to appropriately substantiate a health effect must be primarily based on human trials that assess the intended substance (bovine lactoferrin) in the target population (healthy formula-fed infants). FSANZ identified three studies that met these relevancy principles (noting, a fourth study was identified but was not considered as the study subjects were anaemic and not representative of the general infant formula population). While on balance the human intervention trials suggest infant formula supplemented with bLf may benefit infants through reduced risk and duration of illness, the evidence base is very small, and as noted by FSANZ, the quality of evidence was also weak.

Given the limited evidence base, there is potential that future studies may readily overturn the weight of evidence. For this reason, **the departments' support for the progression of Application A1253 is contingent on the evidence for a health benefit in infants being re-examined and the permission reviewed after a reasonable period of time**. We suggest a review period of 5 years, which is consistent with A1155 and should allow for new evidence to be published. If at the time of review there is a clear substantiated health benefit of bLf, the substance should be mandated for inclusion in infant formula to ensure all infants have equitable access to formula that is as closely aligned as possible to the composition of breastmilk, and the associated health outcomes. Alternatively, if new evidence emerges that contravenes the beneficial role in infants, then a Proposal should be raised to remove the voluntary permission to prevent overburdening infants' systems and the marketing of substances which do not benefit infants. This approach is consistent with the departments' suggested regulatory framework for optional ingredients in response to the Call for Submissions to P1028 in June 2022. We believe this approach appropriately places infant health and safety above industry commercial objectives.

The five-year review would also provide an opportunity to review evidence of the impact of bLf on iron status. While evidence considered by FSANZ in Supporting Document 1 did not identify a significant effect on iron status indicators, we note the number of studies was limited. bLf has been suggested to enhance iron absorption and therefore addition to infant formula could potentially result in infant iron uptake above recommendations. The

departments therefore suggest FSANZ revisits evidence of the effect of bLf on iron status at the five-year review to ensure the compositional requirements for iron in bLf-supplemented infant formula remain appropriate.

Exclusivity

The departments note the Applicant has requested, and FSANZ intends to grant exclusive use of bLf under the brand Synlait for a period of 15 months from gazettal. We also note, according to the record of views of the Advisory Committee on Novel Foods (ANCF), bLf for use in dairy products has been assessed as a traditional food. The departments have been contacted by industry stakeholders concerned that the exclusive permission under A1253 may have unintended consequences for businesses that have made commercial decisions based on the ANCF view. For the avoidance of doubt, we seek clarification as to whether the proposed exclusive permission is limited to infant formula products.

The departments also question whether exclusive use of ingredients in infant formula is appropriate where the substance is shown to benefit infants. The intention of exclusive permissions is to allow businesses to achieve return on investment in developing novel ingredients. However, exclusivity also reduces availability, potentially limiting infant access to beneficial products at the expense of commercial outcomes. We believe this contradicts the high order policy principles set out in the *Food Standards Australia New Zealand Act 1991,* that place the protection of public health and safety as the primary objective in the development of food regulatory measures. It is also inconsistent with the specific policy principles for composition that state the composition of infant formula and follow on formula should strive to achieve as closely as possible the growth and development of breastfed infants, which is not possible where exclusivity is granted. We request FSANZ reconsiders whether exclusivity for bLf in infant formula is appropriate under the Policy Guideline principles.