INFANT NUTRITION COUNCIL
AUSTRALIA & NEW ZEALAND

EXECUTIVE SUMMARY

1. INC supports the need to ensure that infant formula products available in Australia and New Zealand are safe and nutritious. The Call for Submissions for *Application A1253 – Bovine Lactoferrin in Infant Formula Products* ("the **CFS**") proposes that bovine lactoferrin ("**bLF**") be permitted to be voluntarily added to infant formula products at 40mg/100kJ (equivalent to around 1109mg/L) as a nutritive substance.

2. INC strongly supports the voluntary addition of bLF to infant formula products and supports amendment to Standard 2.9.1 of the Australia New Zealand Food Standards Code ("the **Standard**") and related Schedules for this purpose.

3. The level of bLF addition to infant formula products proposed, is up to a maximum of 40mg/100kJ (equivalent to around 1109mg/L). While this is at the lower end of the concentration in human breast milk in Australia, it is entirely consistent with the maximum levels for infant formula products in the legislation of EU, China and Singapore. INC therefore strongly supports the maximum level proposed of 40mg/100kJ of bLF added to infant formula products.

4. The categorisation of bLF as a 'nutritive substance' highlights complexities with this categorisation – whilst bLF contributes important and beneficial properties (anti-viral and anti-bacterial), its classification as a nutritive substance is unclear and open to interpretation. To address this lack of clarity, and in the absence of *Proposal P1024 Novel foods and nutritive substances,* INC recommends that, following conclusion of this Application, FSANZ convenes a workshop of stakeholders to discuss the future application/use of the term 'nutritive substance' and considers the prospect of guidance around its use going forward. This would ensure that the issues presented to the infant formula industry and jurisdictions are also discussed transparently with stakeholders from the wider industry and other stakeholders in public health.

5. In relation to the proposed specification in the Standard (the "**Draft Specification"**), INC considers it 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) and is therefore not fit-for-purpose nor supportive of a balanced regulatory setting insofar as it is specific to a single manufacturer's specification.

6. INC recommends that where there is no EU or China specification for a parameter, the proposed standard for the Food Standards Code should not present a parameter and where parameters are in place in the EU and/or China then these should be preferred. In this way, the regulatory standard for the specification will truly accommodate other brands of bLF by adopting a regulatory standard based on sound principles of safety and thereby avoiding the need for multiple applications requiring many hundreds of hours work by subsequent applicants and FSANZ. In this way also, all stakeholders would be leveraging the learnings from the costly EU experience which ultimately delivered a broad regulatory standard for all manufacturers.

7. The principle for regulatory best practice is that a regulatory standard should present minimum effective regulation. In INC's view, FSANZ has not applied this principle insofar as the Draft Specification, especially for the burden of contaminants, will be the tightest regulatory standard for bLF in the world.

8. Finally, INC is supportive of the concept of exclusive capturable commercial benefit and fully recognises the value that this must deliver on investment for the food industry and for innovation. We are concerned, however, at the ad hoc way in which the concept appears to be implemented and suggest a more consistent approach be applied to ensure visibility for the broader food industry.

DETAILED COMMENTS

Support for voluntary addition of bLF to infant formula products

9. INC 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 the Standard for this purpose.

10. bLF is widely used globally and has a long history of safe use in infant formula internationally. It is significant that infants in many other countries and regions already benefit from the voluntary addition, and we note that first infant formula product containing bLF was released in Japan in 1986[1].

Maximum level of addition of bLF in infant formula products

11. Lactoferrin is a protein found in human breast milk at a concentration of 1230-3390 mg/L as reported in the CFS. The higher levels appear to reflect the levels in very early maternal milk rather than mature breast milk. This can be seen in the levels reported for well-nourished Australian women (at more than 15 days post-partum) as 1230-1420 mg/L[2].

12. In mammalian milks (cow, goat and sheep) the concentrations as reported in the CFS are much lower at 80-177 mg/L (cows' milk) and 17-166 mg/L (goat and sheep milk). INC notes that, as with human milk, the bLf concentrations in mammalian milk can vary depending on the animal and stage of lactation but a typical concentration value of 100 mg/L covers all. We note the content of bLf in standard, made-up infant formula (unfortified with lactoferrin) to be 10-27 mg/L.

13. The level proposed is at the lower end of the concentration in mature human breast milk and is a level consistent with the maximum levels for infant formula products in the legislation of the EU, China and Singapore. Taking these factors into account, INC strongly supports the maximum level proposed of 40mg/100kJ of bLF added to infant formula products.

bLF as a 'nutritive substance'

14. INC notes that bLF for addition to infant formula products at levels up to 40mg/100kJ has been proposed as a nutritive substance. A key benefit of bLF to infants is its anti-viral and anti-bacterial properties, as demonstrated in numerous research studies cited in the CFS. This is the core of its significance for addition to infant formula products so that the infants who are not breastfed, can benefit from these properties that are otherwise available to the breast fed infant.

15. The classification of nutritive substances (and novel foods) appears open to interpretation and INC supports reactivation of P1024 to provide industry and stakeholders regulatory clarity. In the absence of the completion of P1024, INC recommends that, following

[1] Section 3.1.4 Post market surveillance, SD1

[2] Rai D, Adelman AS, Zhuang W, Rai GP, Boettcher J, Lönnerdal B. (2014). Longitudinal changes in lactoferrin concentrations in human milk: a global systematic review. Critical Reviews in Food Science and Nutrition, 54(12), 1539-1547. doi:10.1080/10408398.2011.642422

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 around its use going forward, as an interim measure until P1024 is reactivated and concluded. This would ensure the issues presented to the infant formula and wider food industries and jurisdictions are also discussed transparently with stakeholders from the wider industry.

Specification

16. We note the EU first issued an opinion on bLF for one company ten years ago (2012) and subsequently (until in 2018) several other companies were granted 'substantial equivalence' for the bLF products they manufactured on application. In 2018, this mechanism was replaced by an updated regulation[3] allowing any bLf that met the EU specification for bLf as listed in the EU list of authorised novel foods[4] to be used within the EU. This last development was a sensible approach and saved many hundreds of hours work by subsequent applicants, stakeholders and EU governments.

17. The CFS and the applicant both state that the industry will be able to use the permission in due course. The CFS states that "the permission would apply to all brands of bLf in accordance with the Code"[5] (INC emphasis). This is not completely true. FSANZ has taken some elements of the applicant's manufacturing specification and, while explaining why some are not taken up (eg microbiological elements), it is not clear why others have been taken up when neither of the two international standards contain the elements and no risk assessment of the need for, or level of, the elements has been conducted. The result is a limitation on the broader use for other brands of bLF that do not meet the specification in the future, irrespective of any other conditions on access.

18. In short, the Draft Specification 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). INC recommends

    a. that where there is no EU or China specification for a parameter, the proposed standard for the Australia New Zealand Food Standards Code should not present a parameter. This would omit parameters for fat, solubility, cadmium, mercury, aflatoxin, melamine, aluminium, nitrate and nitrite.
    b. Where parameters are in place in the EU or China then these limits should be preferred.
    c. Where parameters are in place in the EU and China, then the more stringent should be preferred.
    d. Specifically, we recommend that the Iron content is amended to < 35 mg/100g to align with EU and China regulatory limits.

19. The principle for regulatory best practice is that a regulatory standard should present minimum effective regulation. In INC's view, FSANZ has not applied this principle, insofar as the Draft Specification , especially for the burden of contaminants, will be the tightest regulatory standard for bLF in the world. The above recommendation would present the minimum effective regulation.

20. The Draft Specification will actually prevent, in perpetuity, the use of the Standard by many other companies. We do not believe this serves the industry, consumers or governments well since any other manufacturer will, as was the case in the EU between 2012 and 2018,

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R2283
[4] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R2470&from=EN
[5] CFS, section 2.2.10, 5th paragraph

need to go through the resource-intensive process of submitting an application where there is a variation to the standard specified in the regulations. This would appear to be an inefficient and laborious approach creating unnecessary technical barriers to market entry.

21. The INC prepared a comparison of the parameters in the EU, China, the Application[6], the CFS and SD1 (Attachment A) the outcome of which show:
    - It is not clear what principles FSANZ has applied to make its decisions about inclusion or exclusion of parameters eg there are many parameters in the Draft Specification that do not appear in the EU or China regulations
    - Some references to "greater than" or "greater than or equal to" appear random – not based on other specifications or the Application. The differences between "greater than" and "greater than or equal to" are important.
    - Trade impacts of such a detailed specification are high
    - There may be an error in relation to iron whereby the CFS refers to 15g/100g and SD1 refers to 15mg/100g.

22. Applying the principle of regulatory best practice described above, INC recommends the Draft Specification is amended as shown in Attachment A.

23. We would also point to the current FSANZ Corporate Plan[7] that states under the heading of 'Effective, efficient and fit-for-purpose standards' that FSANZ:
    "… *will continue to ensure standards are proportionate, fit-for-purpose and well designed to support balanced regulatory settings, maintain essential safeguards and reduce compliance costs*".

24. The Draft Specification does not meet this bar set by FSANZ itself. It is not fit-for-purpose nor supportive of a balanced regulatory setting nor reductive of compliance costs insofar as it favours a single manufacturer's specification which may not be met by other manufacturers. INC recommends a broader specification for the Standard that will truly accommodate other manufacturers of bLF in the future, in alignment with the EU and China approach. In this way we would be leveraging the learnings from the costly EU experience and saving similar costs across the board in this region.

Exclusivity

25. INC is not commenting on the specifics of the exclusivity proposed either by the applicant or in the CFS.

26. INC is supportive of the concept of exclusivity and recognises the clear benefits it delivers to innovation and research and development and advocates the continuation of the facility. However, when exclusivity emerged as a concept in 2007 in the final assessment report on *Proposal P305 Permission for exclusivity of use of novel foods*[8], it was for data protection and to remove the potential for competitors to take advantage of FSANZ's transparent processes upon gazettal of an amended standard:
    "*That is, a competitor is able to access the information relevant to the application and undertake product development to coincide with the gazettal of an approved novel food, thus removing the benefit for the applicant*."

27. To be clear, INC is supportive of the concept of exclusive capturable commercial benefit and fully recognises the value that this must deliver on investment for the food industry

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[6] Drawn from Table 2-8 in *Application to permit the optional use of bovine lactoferrin in infant formula products*, Synlait, April 2022

[7] Corporate Plan 2022-23 (foodstandards.gov.au)

[8] Microsoft Word - P305 Novel Food exclusivity FAR FINAL.doc (foodstandards.gov.au)

and for innovation. We are concerned, however, at the ad hoc way in which the concept appears to be implemented and suggest a more consistent approach be applied (such as through an industry workshop on exclusivity) i to ensure visibility for the broader food industry.

Attachment A

Comparison of parameters from EU, China, Synlait Application, CFS and SD1

Parameter	EU	China	Synlait	CFS	SD1	Recommendation
Physical and Chemical Parameters						
Description	Virtually odourless, light pinkish powder	Pale pink to reddish brown powder	Pink to reddish brown coloured, free-flowing powder	Pink to reddish brown coloured, free-flowing powder	Pink to reddish brown coloured, free-flowing powder	Align with EU or China
Protein	> 93.0%	> 93.0%	≥ 95.0 g/100g	more than 95.0%;	> 95.0%	Align with EU or China
Purity (on a protein basis)	> 95.0%	≥ 95.0%	≥ 95.0% of protein	more than 95.0%[9]	>95.0%	Support
Moisture (loss on drying)	<4.5%	≤4.5%	≤ 4.5 g/100g	less than 4.5g/100g	< 4.5 g/100g	Support
Ash	< 1.5%	≤2.0%	≤ 1.3 g/100g	not more than 1.3g/100g	≤1.3 g/100g	Align with EU
Fat	-	-	≤1 g/100g	not more than 1g/100g	≤1 g/100g	Remove
Arsenic	< 2.0 mg/kg	≤ 1 mg/kg	≤ 0.020 mg/kg	not more than 0.02 mg/kg	≤0.02 mg/kg	Align with China
Lead	-	≤ 1 mg/kg	≤ 0.020 mg/kg	not more than 0.02 mg/kg	≤ 0.02 mg/kg	Align with China
Iron	< 350 mg/kg	< 35 mg/100g	≤ 15 mg/100g	not more than 15g/100g	≤15 mg/100g	Align with EU and China
pH (10% solution)	5.2 to 7.2	5.2 to 7.2	5.2 to 7.2	pH (10% solution)—5.2 to 7.2	5.2 –7.2 (10% solution)	Align with EU and China
Solubility (2% solution, 20°C)	-	-	transparent	transparent;	transparent	Remove

[9] "Purity (on a protein basis) – more than 95.0%" means that >95% of protein needs to be bLF

Parameter	EU	China	Synlait	CFS	SD1	Recommendation
Physical and Chemical Parameters						
Cadmium	-	-	≤0.10 mg/kg	not more than 0.1 mg/kg	≤0.10 mg/kg	Remove
Mercury	-	-	<0.10 mg/kg	not more than 0.1 mg/kg;	≤0.10 mg/kg	Remove
Aflatoxin	-	-	<0.05 µg/kg	not more than 0.05 µg/kg	≤0.05 µg/kg	Remove
Melamine	-	-	Not detected	Not detected	Not detected	Remove
Aluminium	-	-	<4.8 mg/kg)	not more than 4.8 mg/kg	≤4.8 mg/kg	Remove
Nitrate	-	-	≤50 mg/kg	not more than 50 mg/kg	≤50 mg/kg	Remove
Nitrite	-	-	≤2.0 mg/kg	not more than 2.0 mg/kg	≤2.0mg/kg	Remove