AUSTRALIAN FOOD & GROCERY COUNCIL

AFGC SUBMISSION

RESPONSE TO:

APPLICATION A1253 – BOVINE LACTOFERRIN (BLF) IN INFANT FORMULA PRODUCTS

8 November 2022

Sustaining Australia

PREFACE

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, beverage and grocery manufacturing sector. The membership of AFGC comprises more than 180 companies, subsidiaries, and associates.

Food, beverage, and grocery manufacturing together forms Australia's largest manufacturing sector, representing 32 per cent of total manufacturing turnover in Australia. This $132 billion sector significantly contributes to the Australian economy and directly employs 270,800 Australians, with many more employed across an expansive supply chain.

The diverse and sustainable industry is made up of 16,000 businesses and accounts for $81 billion of the nation's international trade. These businesses range from some of the largest globally significant multinational companies to small and medium enterprises. Industry made $2.8 billion in capital investment in 2018-19.

Many food manufacturing plants are located outside the metropolitan regions. The industry makes a large contribution to rural and regional Australia economies, with almost 40 per cent of the total persons employed being in rural and regional Australia.

It is essential to the economic and social development of Australia, and particularly rural and regional Australia, that the magnitude, significance, and contribution of this industry is recognised and factored into the Government's economic, industrial and trade policies.

In Australia, the food and beverage (grocery was not included in the Government's strategy but is recognised as a vital industry) manufacturing sector has been confirmed as an essential service and a National Strategic Priority.

The Australian Government through its recently announced Manufacturing Strategy has challenged the sector to develop an industry roadmap describing how it will contribute to the post-COVID-19 recovery through expanding manufacturing, growing jobs, boosting exports, and enhancing sovereign capability across the sector.

Food and beverage manufacturing plays an integral role in Australia's economic and social fabric. It is the lifeblood of many regional and rural communities. As such it is well placed to do the heavy lifting in the Manufacturing Strategy through its size, its know-how in adding value to the commodities of the agricultural sector, and to leverage the reputation for safety and quality among consumers in overseas markets.

This submission has been prepared by the AFGC and reflects the collective views of the membership.

OVERVIEW

The Australian Food and Grocery Council (**AFGC**) appreciates the opportunity to respond to *A1253 Bovine lactoferrin in infant products*[1].

Synlait Milk Ltd, The Applicant, has applied to Food Standards Australia New Zealand (**FSANZ**) to amend the Australia and New Zealand Food Standards Code (**the Code**) to permit the voluntary use of bovine lactoferrin (**bLf)** as a *nutritive substance* in infant formula products (**IFPs**). The Applicant has also requested an exclusive use permission whereby bLf under the brand "Synlait" could only be sold for use as a *nutritive substance* in an IFP for a period of 15 months. FSANZ seeks comment on a prepared draft variation of the code.

GENERAL COMMENTS

The AFGC supports government policies for the protection and promotion of breastfeeding and recognises the role of scientifically developed infant formula product as the only suitable and safe alternative when breast milk is unavailable for an infant.

In response to the Consultation, the AFGC has had the opportunity to review the submission to this consultation by the Infant Nutrition Council of Australia and New Zealand (**INC**). The AFGC **strongly supports** the INC positions as stated in its submission and shares the concerns that the INC has described in detail.

The AFGC is **strongly supportive** of the permission to voluntarily use bLf up to a maximum of 40mg/100kJ (equivalent to around 1109mg/L) and supports amendment to Standard 2.9.1[2] of the Code for this purpose in IFPs. However, while supporting the permission to use bLf in IFPs, it questions the permission proceeding under the current condition i.e. bLf as a *nutritive substance*, given the difficulties and uncertainties in applying the Code's definition of "Nutritive Substance". The AFGC recommends as a priority that FSANZ clarify the definition of *nutritive substance* prior to the completion of the consultation process through stakeholder engagement. Without a clear definition, complexity and confusion arises as the food industry finds it difficult to innovate and bring to market foods that provide benefits to consumers, and the jurisdictions are inconsistent in their approach to enforcement. It is not the role of the food industry to discern differences in terminology of food components. It is incumbent on the regulator to provide clarity.

The AFGC seeks further clarity on the grounds by which exclusivity is granted, and to better understand if substantial innovation has been required by The Applicant to manufacture bLf, and therefore afford 15 month period of exclusivity. The AFGC notes The Applicant has been manufacturing bLf for over a decade (since 2011) during which time commercial benefit may have offset initial investment. Further, the manufacture of bLf is not new to the Australian and New Zealand dairy industry and there is a long and

[1] A1253 - Bovine lactoferrin in infant formula products (foodstandards.gov.au)

[2] Federal Register of Legislation - Australian Government Standard 2.9.1

safe history of use internationally. General improvements in The Applicant's manufacturing facilities and payment of regulatory fees is not clearly linked to innovating and developing new products.

SPECIFIC COMMENTS

The AFGC wishes to make the following specific comments in relation to this application.

Support for voluntary addition of bLf

The AFGC is **strongly supportive** of the permission to voluntarily use bLf up to a maximum of 40mg/100kJ (equivalent to around 1109mg/L) and supports amendment to Standard 2.9.1 of the Code for this purpose in IFPs.

However, the AFGC questions whether the application should proceed under the current conditions i.e. bLf as a *nutritive substance*, and it instead recommends that FSANZ, as a priority, clarify the definition of *nutritive substance* prior to the completion of the consultation process through stakeholder engagement. There are implications, discussed below in detail, regarding current use of bLf in general foods and toddler milks, as well as difficulties and uncertainties in applying the Code's definition of "Nutritive Substance".

Clarification of Nutritive Substance Definition

The AFGC considers the Code's definition of *Nutritive Substance* to be unclear, difficult to interpret and enforce, and is misaligned with other regulatory jurisdictions such as the European Union (**EU**) where the focus is on the safety of an ingredient.

It is important to note that the ambiguity of the definition of *nutritive substances* dates back to 2008[3] in which the NSW Supreme Court identified a number of ambiguous terms in the definition that made interpretation very difficult.

"The definition includes terms that are themselves not clearly defined. In particular, terms like normally consumed, nutritive purpose and ingredient are not defined in the Code. The lack of clear meaning of these terms creates uncertainty and ambiguity in the overarching definitions of nutritive substance. This uncertainty and ambiguity makes it difficult to be certain which substances and foods should be considered nutritive substances and therefore, whether particular substances require specific permission in the Code before they can be added to, or sold as, foods".

AFGC notes a key definition in the CfS (p7) of a *nutritive substance*, as follows:

A substance is used as a nutritive substance in relation to a food if it is added to the food to achieve a nutritional purpose; and it is a substance identified in subsection 1.1.2—12(2) of the Code.

[3] Consultation Paper Proposed Future Regulation of Nutritive Substances and Novel Foods in the Australia New Zealand Food Standards Code. P5
https://www.foodstandards.gov.au/media/Documents/Regulation%20of%20Nutritive%20Substances%20and%20Novel%20Foods%20Consultation%20Paper%20FINAL.pdf

The substances identified in subsection 1.1.2—12(2) are:

(a) any substance that is identified in this Code as one that may be used as a nutritive substance; and

(b) a vitamin or a mineral; and

(c) any substance (other than an inulin-type fructan, a galactooligosaccharide or a substance normally consumed as a food) that has been concentrated, refined or synthesised, to achieve a nutritional purpose when added to a food.

As the Code is silent on the definition of *nutritional purpose*, it results in an ambiguous and inconsistent approach to interpretation by FSANZ and enforcement agencies, when approval is needed in the Code for substances added for purposes other than essential nutrition (e.g. health effects).

The AFGC supports the INC's recommendation to FSANZ to consider convening a workshop of stakeholders to discuss the future application/use of the term *nutritive substance* and consider guidance of its use going forward.

Additionally, the AFGC **supports** the ongoing *P1024 – Revision of the Regulation of Nutritive Substances and Novel Foods*[4] and, longer term, supports removing the *nutritive substance* definition to align with other regulatory approval processes more closely such as the EU or the United States (**US**). The AFGC understands that there is a prohibition on the addition of novel foods and nutritive substances unless the Code expressly permits the addition.

Implications for use of bLF in IFP

The AFGC seeks clarification of the definition of *nutritive substance* as FSANZ has accepted the application in which bLf is defined as a *nutritive substance.*

The AFGC recognises that an ingredient can be classed as novel for use in foods for infants, but not novel for the general population. The Advisory Committee on Novel Foods (**the ACNF**) has previously found that bLf was **not** a *novel food* in the application of adding 10-100mg to 100g or 100mL of dairy products. The ACNF deemed it a *traditional food* under this condition[5], **See table 1.** Therefore, the classification of bLf as a *nutritive substance* for use in IFP could cast doubt and create confusion around its use in general foods.

Although there is no history of consumption of lactoferrin in non-dairy foods in Australia, it may be reasoned that its addition to non-dairy foods at similar levels 10-100 mg/100mL or 100g would raise no issues requiring an assessment of public health and safety.

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[4] Proposal P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods
https://www.foodstandards.gov.au/code/proposals/Pages/P1024.aspx

[5] FSANZ Record of views formed in response to inquiries Updated August 2022
https://www.foodstandards.gov.au/industry/novel/novelrecs/Documents/Record%20of%20views%20updated%20August%202022.pdf

Table 1 Excerpt from the FSANZ Advisory Committee on Novel Foods

Food or food ingredient	Outcome View	Justification/Comment
Lactoferrin (Bovine) for use in dairy products at 10-100 mg/100mL or 100 g	• Traditional food • Not novel food	Normal constituent of bovine milk at 20-200 µg/mL (2-20 mg/100 mL). Proposed use in yoghurt is within the normal range of dietary intake of lactoferrin from dairy foods in the diet.

The AFGC notes according to *Standard 1.1.1 Structure of the Code and general provisions*[6], unless expressly permitted, a food for sale must not have as an ingredient or component, a substance that was used as a *nutritive substance* (as defined in section 1.1.2—12)[7]. According to the Call for Submission (**CfS**), it states (p4) that

"*bLf would be a substance used as a **nutritive substance** for the purposes of the Code because its proposed addition to IFP is intended to achieve specific nutritional purposes.* "

The CfS states bLf has the beneficial purpose of reducing risk of infection (p4)

*Based on FSANZ's assessment of **beneficial health effects**, FSANZ concludes that bLf is bioavailable in infants and performs a similar nutritional function to hLf in meeting the stated beneficial purpose of reducing risk of infection in infants.*

According to the Code *Standard 1.2.7 - Nutrition, health and related claims*[8], defines a *health effect* as an effect on the human body, including an effect on one or more of the following

(a) a biochemical process or outcome
(b) a physiological process or outcome
(c) a functional process or outcome
(d) growth and development
(e) physical performance
(f) mental performance
(g) a disease, disorder or condition.

The AFGC seeks clarity on the addition of a substance to achieve a *health effect/s* and whether this does or does ***not*** amount to use as a *nutritive substance*.

The AFGC has issue with the ambiguity of the definitions of these terms and the critical importance of determining the purpose of adding a substance to a food, i.e., is it for nutritional purpose or health effect or is it both.

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[6] Federal Register of Legislation - Australian Government Standard 1.1.1 Structure of the Code and general provisions

[7] Federal Register of Legislation - Australian Government Standard 1.1.2 Definitions used throughout the Code

[8] Federal Register of Legislation - Australian Government Standard 1.2.7 - Nutrition, health and related claims

Implications for use of bLf in general foods

If FSANZ deems bLf to be a *nutritive substance*, there will be an impact on the general food industry as it raises the question that bLf (in isolated form) may not be permitted to be added to other food categories **and** being used for the same purpose in any other unapproved food.

If the application of '*nutritive substance'* were to extend beyond IFPs to also apply to general purpose foods, the implication of this is that manufacturers will be required to lodge an application to FSANZ for approval, for every additional food it wishes to add lactoferrin to as an ingredient. Additionally, there will be a significant cost and administrative burden from this outcome, especially for those manufacturers which currently have bLf-containing food products on the market. Their products will be in breach of the Code and will require withdrawal from the market, and potentially reformulation and re-labelling.

The AFGC wishes to clarify with FSANZ if the Code **permits** the same food or substance being added for more than one *purpose, whether these are purposes requiring premarket approval or are un-regulated.*

Amend proposed Specification

Given that there are already existing specifications for bLf (China and EU), the AFGC does **not** support the proposed specification in the Code.

Further, the specification provided in the draft variation to Schedule 3 - Identity and Purity (the **Draft Specification**) contains unnecessary parameters. The Draft Specification appears, in regard to a number of parameters, to be almost a replica of The Applicant's manufacturing specification, rather than the identity and purity measures needed to meet the regulatory standard and the Code's objectives. The Draft Specification is also, crucially, misaligned with EU and China regulatory standards.

The AFGC is concerned that in replicating many parameters in The Applicant's manufacturing specification, industry will be faced with a specification that is far more restrictive than is necessary to meet food safety objectives. And, as a result, the Draft Specification, if enacted, risks excluding sales of products that contain lactoferrin which is safe but does not otherwise meet an unnecessary part of the specification.

By way of example, under the current Draft Specification, a maximum iron content of 15mg/100g limit may restrict manufacturers from using as an ingredient current lactoferrin, the specification of which, aligns with international regulatory standards and is deemed to be safe. The Draft Specification's iron content limit does not accommodate the range achieved through the use of currently available processing technologies, let alone future innovations. We therefore recommend amending the iron content maximum to <35mg/100g to align with EU and China regulatory standards. As an aside, the CfS states Iron Max 15**g**/100g whereas SD1 says 15**mg**/100g. The AFGC response is based on the assumption that the level stated in the CfS is intended to be 15**mg**/100g.

Lastly, while manufacturers could file additional applications with less restrictive specifications than currently proposed under this permission, the AFGC notes that would create additional administrative burdens on FSANZ and industry, whilst achieving no added public health protection.

Thus, this additional burden is neither necessary nor justified in this circumstance. Note that the CfS p13 states the following:

FSANZ must

"*have regard to **consistency** between domestic and international food standards when developing or varying standards*" and that *"alignment with regulations such as those from the European Union (EU) are particularly relevant for the trade of products to and from Australia and New Zealand."*

In summary, the Draft Specification does not promote consistency with international standards as demonstrated by Table 2-10 of The Application which shows discrepancies between parameters included in the draft variation and also maximum iron, lead and arsenic limits which may exclude lactoferrin that is compliant with EU and China regulatory standards, leaving open the possibility that Australia and New Zealand could be challenged under the World Trade Organization agreements.

Exclusivity period

The AFGC notes that in the CfS (p15) that an exclusive use permission for bLf for a period of 15 months has been requested by The Applicant on the basis that they have invested "significantly" in the technology development and safety studies (although the latter reason is not stated in the application, per se).

In the Application, the reasons for exclusivity are stated (p21),

"Synlait has made significant investment in the development of a high-quality bovine lactoferrin ingredient suitable for infant application, and in state-of-the art manufacturing facilities. Synlait also committed significant resource in drafting this application and is paying the applicable fees in full. Synlait therefore requests for Exclusivity to be granted, enabling Synlait to capture an Exclusive capturable commercial benefit."

And

"Obtaining Exclusivity will enable Synlait's customers to be the first in the market to provide a differentiated product containing bLf and to be able to align their international product portfolio."

On the basis that the AFGC argues that there is insufficient evidence of novel technology, we do **not** support granting of 15 months exclusivity, in this instance.

The AFGC acknowledges the time required to make formulation and artwork changes to IFPs, but it also notes in the CfS (p23) that The Applicant and other parties have been manufacturing and selling bLf for some years in the Chinese market therefore it is not clear how exclusive use in the ANZ market is justified.

"The applicant has been manufacturing IFP containing bLf for the Chinese market since 2011 and using its own internally manufactured bLf since 2014 (GRN669, 2016)."

The AFGC notes that under FSANZ Act (1991)[9], section 8

"*An **exclusive capturable commercial benefit** is conferred upon a person who applies for the development of a food regulatory measure or the variation of a food regulatory measure under section 22 if:*

[9] Food Standards Australia New Zealand Act 1991 (legislation.gov.au)

> *(a) the applicant can be identified as a person or body that may derive a financial gain from the coming into effect of the draft standard or draft variation of the standard that would be prepared in relation to the application; and*
>
> *(b) any other unrelated persons or bodies, including unrelated commercial entities, would require the agreement of the applicant in order to benefit financially from the approval of the application*."

Also, under section 146 (6)

"*A charge may be fixed in relation to an application to develop or vary a standard only if:*

> *(a) the development or variation of the standard would confer an exclusive capturable commercial benefit on the applicant; or*
>
> *(b) the applicant has elected to have the consideration of the application expedited."*

Given the fact that numerous lactoferrin products are already being manufactured which have a history of safe use around the world, including in IFP, the only basis on which exclusivity can be conferred on The Applicant in order to provide a capturable commercial benefit is by detailing in the variation The Applicant's product specifications. The AFGC is not convinced this alone is sufficient justification for conferring exclusivity. Moreover, the AFGC is concerned that it may create a precedent for future decisions when applications are made seeking variations to the Code.

The original intent of concept of *exclusive capturable commercial benefit* was to specify a condition under which FSANZ (or to be precise its predecessor the Australia New Zealand Food Authority; **ANZFA**) could impose a charge on an Applicant seeking a variation for a new technology (i.e. additive, processing aid) health claim, *the exclusivity of which was already protected by patents or commercial secrets.*

CONCLUSION

The AFGC is of the strong view that this application (A1253) has brought into sharp relief the opaqueness of FSANZ's thinking regarding:

1. definitions of the related concepts of *nutrition substances, nutritional purpose* and *health effects;* and
2. exclusivity and the circumstances under which *exclusive capturable commercial benefit* is granted to Applicants seeking variations to the Food Standards Code.

The AFGC considers it is incumbent upon FSANZ to remove the opaqueness around these concepts as soon as possible, and to provide greater certainty to industry as it seeks to introduce new, innovative products to the market.

The AFGC **supports** the INC's recommendation to FSANZ to consider a review of the concept of exclusivity following this Application.

The AFGC asserts that the assessment criteria by which an applicant may be granted exclusivity is not clear or transparent. Stakeholder consultation would be of benefit in clarifying the grounds by which exclusivity is granted. The AFGC wishes to understand the true basis of exclusivity as a simple innovation

based on existing public knowledge is different to a substantial inventive (new) step in product, process or invention, as is required in patency law[10].

The AFGC stands ready to assist FSANZ in securing definitions which make sense technically, are practical for industry to work with, are readily enforceable and, most importantly, create a clear regulatory pathway for new products designed to help consumer construct diets better able to protect and promote good health.

SUMMARY

The AFGC **supports** breastfeeding due to the numerous maternal and infant benefits derived from breast milk. However, for infants that are unable to receive breast milk, infant formula that is based on the latest evidence-based science is the best alternative.

The AFGC **supports** FSANZ's efforts to update the infant formula standards to better meet the needs of stakeholders, and particularly the infant formula manufacturing industry and the consumers/caregivers of infants it serves.

The AFCG **strongly supports** the permission to voluntarily use bLf up to a maximum of 40mg/100kJ and amendment to Standard 2.9.1 of the Code for this purpose in IFPs.

However, in relation to A1253, the AFGC **questions** the regulatory fit of the application that bLf is a *nutritive substance*. The AFGC strongly recommends that FSANZ clarify the definition of *nutritive substance*. The AFGC **supports** the ongoing P1024 review of the Nutritive Substances and Novel Foods and, longer term, supports removing the *nutritive substance* definition to align other regulatory approval processes more closely such as the EU or US.

The AFGC **does not support** granting a 15 month exclusivity period, given The Applicant has been manufacturing bLf for over a decade (since 2011) during which time commercial benefit may have offset initial costs. A review of the concept of exclusivity is recommended.

In relation to the Draft Specification, the AFGC **does not support** the proposed specification in the Code and recommends that the standard for Identity and Purity is aligned EU and China regulatory standard to facilitate trade.

Lastly**,** if bLf is deemed to be a *nutritive substance*, there will be an impact on the general food industry as bLf (in isolated form) will not be permitted to be added to other food categories, nor be used for the same purpose in other unapproved food(s). Manufacturers will be required to lodge an application to FSANZ for approval, for every additional food it wishes to add bLf to as an ingredient.

[10] Queensland Government. Business Queensland. What is a patent. https://www.business.qld.gov.au/running-business/protecting-business/ip/types/patents/definition

Additionally, there will be significant cost for those manufacturers which currently have lactoferrin-containing food products on the market as these products will be in breach of the Code and will require withdrawal from the market.

RECOMMENDATIONS

The AFGC

- **Supports** the permission to voluntary use bLf in IFPs up to a maximum of 40mg/100kJ, and associated amendment of the Standard 2.9.1
- **Queries** the application proceeding under the current conditions that bLF is a *nutritive substance*.
- **Recommends** that FSANZ consult with external stakeholders prior to the completion of the application for the addition of bLF to IFPs on
    - clarifying the definition of *nutritive substance* through stakeholder consultation.
    - reviewing the concept of exclusivity following this Application.
- **Recommends** the proposed specification for Schedule 3 Identity and Purity be revised to be appropriately generic and internationally aligned.
- Does **not support** the granting of exclusivity in this instance

[redacted]

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