

16 February 2023
[231-23]

Approval report – Application A1253

Bovine lactoferrin in infant formula products

Food Standards Australia New Zealand (FSANZ) has assessed an Application made by Synlait Milk Ltd. (the Applicant) to amend the Australia New Zealand Food Standards Code to permit the voluntary use of bovine lactoferrin as a nutritive substance in infant formula products.

On 6 October 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received nineteen submissions and one late submission.

FSANZ approved the draft variation on 1 February 2023. The Food Ministers' Meeting was notified of FSANZ's decision on 16 February 2023.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk Assessment - Risk, benefit and technical assessment

Executive summary

Food Standards Australia New Zealand (FSANZ) assessed an Application from Synlait Milk Ltd. (the Applicant) to amend the Australia New Zealand Food Standards Code (the Code) to permit the voluntary addition of bovine lactoferrin (bLf) as a nutritive substance in infant formula products (IFP) up to a maximum permitted amount of 40 mg/100 kJ. bLf use as a nutritive substance in IFP is currently not permitted in the Australian and New Zealand food supply and any addition in IFP requires express permission via an application to FSANZ to amend the Code. The Applicant also requested an exclusive use permission for their brand of bLf for a period of 15 months after gazettal.

Lactoferrin (Lf) is an iron-binding protein that is naturally present in the body. Lf is present in mammalian milks, notably at high levels in human milk (1230-3390 mg/L), at significantly lower levels in bovine milk (~100 mg/L), and at low levels in infant formula products not fortified with bLf (~15 mg/L). The purpose for adding bLf to IFP is to more closely reflect the Lf content in human milk, and to provide a reduced risk of infection in formula-fed infants.

bLf is derived from cow's milk which is a food allergen. The allergenicity assessment concluded that there is evidence some individuals with cow's milk allergy have IgE antibodies to bLf, indicating sensitisation. FSANZ's risk and technical assessment identified no additional public health and safety concerns with the addition of bLf to IFP up to a maximum permitted amount of 40 mg/100 kJ.

FSANZ also undertook an assessment to substantiate the beneficial role in accordance with the relevant Ministerial Policy Guidelines¹ which found results from *in vitro* and animal studies supporting a plausible mechanism by which bLf can reduce the risk of bacterial and viral infection. FSANZ found that the proposed maximum permitted amount of 40 mg/100 kJ brings bLf in IFP closer to human lactoferrin (hLf) levels in mature human milk, aligns with relevant international regulations and adds only that which is necessary to achieve a potential beneficial outcome.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 6 October 2022 to 10 November 2022. Nineteen submissions were received, all of which FSANZ had regard to (see Section 2.1 of this Report for details of submissions made).

After consideration of submissions and for the reasons summarised in this Report, FSANZ approved the draft variation to the Code with minor amendments to the identity and purity specification. The approved draft variation will permit the voluntary addition of bLf as a nutritive substance in IFP in accordance with the Code. Specifically, the approved draft variation will amend:

- the table to section S29—5 of the Code to permit bLf for use as a nutritive substance in IFP up to a maximum permitted amount of 40 mg/100 kJ;
- Schedule 3 to include identity and purity specifications for bLf with which bLf that is used as a nutritive substance in IFP would have to comply;

¹ [Policy guideline on infant formula products](#) and [Policy guideline on intent of Part 2.9 of the Food Standards Code - special purpose foods](#).

- Standard 2.9.1 and Schedule 29 to: provide that substances may be permitted for use as a nutritive substance in IFP subject to conditions; and set a condition that, for a limited period of 15 months from gazettal of the draft variation, only bLf under the brand Synlait may be used as a nutritive substance in IFP.

Existing labelling requirements in Standard 2.9.1 apply where relevant.

1 Introduction

1.1 The Applicant

Synlait Milk Ltd. is a dairy and food products manufacturer.

1.2 The Application

Synlait Milk Ltd. (the Applicant) submitted an Application to amend the Australia New Zealand Food Standards Code (the Code) to permit the voluntary addition of bovine lactoferrin (bLf) as a nutritive substance in infant formula products (IFP), including infant formula, follow-on formula and infant formula for special dietary use.

Lactoferrin (Lf) is an iron-binding protein that is naturally present in the body. The Application reported it is present in mammal milks, notably at high levels in human milk (around 1230-1420 mg/L in Australian mothers), at significantly lower levels in bovine milk (~100 mg/L), and at low levels in IFP not fortified with bLf (~15 mg/L).

Human lactoferrin (hLf) and bLf are not identical, however the reported differences in structure result in only small differences in cellular uptake and functionality, and bLf has been shown to provide physiological outcomes similar to those provided by hLf. The Application stated that bLf has a history of safe consumption by humans and that bLf can reduce the risk of infections in infants without potential adverse effects.

The proposed permission would allow the voluntary addition of bLf for use as a nutritive substance, at a maximum permitted amount of 40 mg/ 100 kJ, to IFP in accordance with the Code.

1.3 The current standards

1.3.1 Australia and New Zealand

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements in the Code relevant to this Application are summarised below.

1.3.1.1 Permitted use

Paragraph 1.1.1—10(6)(b) of Standard 1.1.1 requires that, unless expressly permitted, a food for sale must not have as an ingredient or component, a substance that is used as a nutritive substance. This requirement extends to foods that are IFP.

Section 1.1.2—12 sets out when a substance is used as a nutritive substance for the purposes of the Code. It provides that a substance is *used as a nutritive substance* in relation to a food if each of the following criteria are met:

- It is added to that food.
- It is added to that food to achieve a nutritional purpose.

- It is a substance identified in subsection 1.1.2—12(2). The substances listed in that subsection include ‘any substance ... that has been concentrated, refined or synthesised to achieve a nutritional purpose when added to a food’.

1.3.1.2 Identity and purity

Section 1.1.1—15 requires that a substance that is *used as a nutritive substance* must comply with any relevant identity and purity specification set out in Schedule 3. The approved draft variation will insert a specification specifically for bLf into Schedule 3 with which, bLf in IFP would have to comply.

1.3.1.3 Infant formula products

Standard 2.9.1 and Schedule 29 set specific compositional and labelling requirements for IFP.

Section 2.9.1—5 provides that a substance listed in Column 1 of the table to section S29—5 may be used as a nutritive substance in an IFP provided that:

- (a) it is in a permitted form listed in Column 2 of that table; and
- (b) the amount of the substance in the IFP (including any naturally-occurring amount) is no more than the corresponding amount listed in Column 4 of that table.

bLf is not listed in the table to section S29—5.

1.3.1.4 Labelling requirements

Subsection 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code for that food. In addition to specific labelling requirements in Standards 2.9.1, the following general labelling requirements also apply.

Division 3 of Standard 1.2.3 sets out the requirements for mandatory declarations of certain foods and their derivatives when they are present in a food for sale².

Standard 1.2.4 generally requires food products to be labelled with a statement of ingredients.

Standard 1.2.7 sets out the requirements and conditions for voluntary nutrition, health and related claims made about food. Paragraph 1.2.7—4(b) states a nutrition content claim or health claim must not be made about an IFP.

Standard 2.9.1 sets out the specific requirements for declaring nutrition information and includes provisions for prohibited representations on IFP labels.

² If a food was packaged and labelled before 25 February 2024, that food may continue to be sold until 24 February 2026 if the food complies with either the previous Code requirements as in force before 25 February 2021, or the amended Code requirements that came into force on 25 February 2021.

1.3.2 Codex standards

The current Codex Alimentarius Standards for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex Standard 72-1981) and for Follow-up Formula (Codex Standard 156-1987) do not contain specific provisions for bLf. However, these standards contain provisions for 'optional ingredients' which would apply to the addition of substances such as bLf. FSANZ notes that the Follow-up Formula Standard is currently under review.³

1.3.3 International regulations

bLf is permitted for use in many infant formula equivalent products overseas. Singapore, China and the European Union each specify a maximum permitted amount of 1000 mg/L of prepared infant formula product. The European Food Safety Authority (EFSA, 2012) cites no observed adverse effects up to the highest dose of 2000 mg/kg bw/day tested in a rat study.

The United States Food and Drug Administration (USFDA) issued a 'no questions' response to Generally Recognised As Safe (GRAS) notice 669 which specifies an intended use level of 100 mg per 100 g of infant formula powder product (USFDA, 2017). This is equivalent to 125 mg/L of prepared infant formula or 135 mg/L of prepared follow-on formula. The GRAS notice acknowledges this intended use level is almost tenfold less than the European Union maximum permitted amount of 1000 mg/L prepared formula, which has a history of safe use. While the notice acknowledges the safety of the higher permission in the European Union, it does not specify why a lower amount was notified, other than that the notifier intended to use this amount and that it was consistent with the amount notified in a previous GRAS notice 465 by another manufacturer of bLf.

Japan, Korea and Taiwan each permit the voluntary addition of bLf to IFP equivalents and do not specify maximum permitted amounts (JETRO, 2011; Ministry of Food and Drug Safety, 2020; Ministry of Health and Welfare, 2022).

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act); and
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved with amendments. The amendments made to the draft variation are explained in Section 2 of this Report. The approved draft variation, as varied after consideration of submissions, takes effect on

³ Currently under review by CCNFSDU. For further information, search on the [Codex Alimentarius website](#).

Gazetta. The approved draft variation is at Attachment A.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on the draft variation to the Code from 6 October 2022 to 10 November 2022. Nineteen submissions were received, four from jurisdictions, fourteen from industry and one from a consumer group. In addition, one late submission was received from an industry body which did not raise any additional issues.

Twelve submissions supported permitting the voluntary addition of bLf to IFP. Several issues were raised in relation to the draft specification, classification of bLf as a nutritive substance, and the granting of an exclusive use permission.

The list of submitters is provided in Table 1 and the key issues raised in submissions and how they have been addressed is provided in Table 2.

Table 1: List of submitters

Submitter	Abbreviation	Submitter type
The a2 Milk Company Limited	a2 Milk	Industry
Australian Food & Grocery Council	AFGC	Industry
Beston Global Food Company Limited	Beston	Industry
Breastfeeding Advocacy Australia	BAA	Consumer
brooke-taylor & co pty ltd	brooke-taylor	Industry
Care A2 Plus Pty Ltd	Care A2+	Industry
Dairy Australia	Dairy Australia	Industry
Fonterra Co-operative Group	Fonterra	Industry
Infant Nutrition Council Australia & New Zealand	INC	Industry
Morinaga Milk Industry Co., Ltd.	Morinaga	Industry
Nestlé Australia Ltd; Nestlé New Zealand Limited	Nestlé	Industry
Noumi Limited	Noumi	Industry
New South Wales Food Authority	NSW FA	Jurisdiction
New Zealand Food & Grocery Council	NZFGC	Industry
New Zealand Food Safety – Haumarū Kai Aotearoa	NZ FS	Jurisdiction
Public Health Services, Department of Health, Tasmania	Tas PHS	Jurisdiction

Synlait Milk Ltd.	Synlait	Industry
The Tatura Co-operative Dairy Company Limited	Tatura	Industry
Victorian Department of Health; Victorian Department of Jobs, Precincts and Regions	Vic	Jurisdiction
Late comment - Dairy Companies Association of New Zealand	DCANZ	Industry

Table 2: Summary of issues

Issue	Raised by	FSANZ response
General concept of adding bLf to IFP		
Generally supportive of permitting bLf to IFP.	A2 Milk, AFGC, Beston, Dairy Australia, Fonterra, INC, Nestlé, NZ FS, NZFGC, Synlait, Tatua, Vic	FSANZ notes this comment.
Maximum/minimum permitted amount		
Support proposed maximum permitted amount of 40 mg/100 kJ.	a2 Milk, AFGC, INC, Nestlé, NZFGC, Synlait, Vic	FSANZ notes this comment.
Support a maximum permitted amount that is equivalent to regulations in major overseas markets of China, Japan and the EU.	Beston, Nestlé, NZFGC, Synlait	FSANZ notes this comment. The proposed maximum permitted amount is 40 mg/100 kJ. This is equivalent to 1109 mg/L, a value similar to the China and EU maximum permitted amounts of 1000 mg/L.
Seek clarification on the rationale for not setting a minimum (rationale given by FSANZ in CFS was related to gut microflora modulation even though FSANZ's	NZ FS	A minimum permitted amount was not requested in the Application and has not been determined by FSANZ. As discussed in this Report and the risk, benefit and technical assessment (SD1), naturally occurring hLf concentrations vary in lactating women.

Issue	Raised by	FSANZ response
assessment didn't include this topic).		<p>Further, FSANZ found that bLf may reduce the presence of potentially pathogenic microflora in both the formula and the gastrointestinal tract. It does not however appear to modulate the host microbiome. Due to individual variations in these three environments FSANZ could not establish a minimum value below which the reduction in pathogenic microflora would not occur. This is consistent with the permissions overseas.</p> <p>This Report and SD1 have been amended to clarify this.</p>
'Nutritive substance' definition and its application		
Support that bLf recovered from milk using ion exchange technology, then pasteurised, filtered, concentrated and spray-dried, be classified as a nutritive substance.	NSW FA, NZ FS, Synlait	FSANZ notes this comment.
Support the permitted form of lactoferrin as 'bovine' and to contain the permission as a nutritive substance in IFP only.	NZ FS	FSANZ notes this comment.
Question the classification of bLf as a nutritive substance. Some submitters cited the Advisory Committee Novel Foods (ACNF)	AFGC, brooke-taylor, Fonterra, Nestlé, Noumi	<p>FSANZ's assessment is that, for Code purposes, the proposed use of bLf constitutes use as a nutritive substance. See Section 1.3.1.1 of this Report.</p> <p>The ACNF decision or recommendation is not relevant in this case. That recommendation relates to use of bLf in general foods and for</p>

Issue	Raised by	FSANZ response
view ⁴ that bLf is considered a traditional food when added to yoghurt at amounts of 10-100 mg/100 mL or 100 g.		the purpose of refortification of small amounts of naturally occurring bLf lost during processing. In that particular context, the ACNF considered bLf to not be a novel food, but a traditional food, when related only to the refortification of bLf. Moreover, the ACNF is not FSANZ. Nor are ACNF recommendations or views binding on FSANZ or represent a FSANZ position or view.
Recommend bLf is recognised as a general food ingredient.	brooke-taylor, Care A2+, Dairy Australia, Noumi	FSANZ notes this comment. See Section 1.3.1.1 of this Report and response above.
The original nutritive substance definition was not intended to apply to any ingredient that has a broad functional property in food.	brooke-taylor	FSANZ notes this comment. See Section 1.3.1.1 of this Report and response above.
<p>Seek clarity on whether the classification of bLf as a nutritive substance in IFP will:</p> <p>a) set a precedent that classifies bLf as a nutritive substance in any food category (e.g. general foods); and/or</p> <p>b) make existing general foods on the market non-compliant if they contain bLf as a</p>	a2 Milk, AFGC, brooke-taylor, Dairy Australia, Nestlé, Noumi, NSW FA, NZFGC	<p>FSANZ remains satisfied that its decision for this Application will not set a precedent for general foods or create regulatory uncertainty.</p> <p>This Application requested permission for the specific use of a specifically concentrated, refined or synthesised product in a specific and limited category of special purpose foods to achieve a specific type of purpose. FSANZ remains satisfied that the specific use in that specific context constitutes use as a nutritive substance for Code purposes – see Section 1.3.1.1 of this Report. The approved draft variation only relates to that specific use in that specific and limited category of foods and for that specific purpose. The draft variation and</p>

⁴ [FSANZ Record of views formed in response to inquiries Updated August 2022](#)

Issue	Raised by	FSANZ response
<p>traditional food (e.g. bLf added to yoghurt); and/or</p> <p>c) cause regulatory ambiguity as to whether an ingredient can be classified differently in different food categories; and/or</p> <p>d) affect the ability of industry to use general level health claims related to bLf in general foods.</p>		<p>permission has no application to bLf use in the general food supply, including for refortification of processed foods.</p> <p>General foods remain subject to the other provisions in the Code that are relevant to general foods.</p> <p>FSANZ was and is required to assess this Application in accordance with the FSANZ Act. This Application and assessment is not the vehicle to review Code provisions and regulatory approaches endorsed by the Food Ministers' Meeting and relating to nutritive substances.</p>
<p>Seek clarity on the definition of 'nutritive substance', including consistency in application of definition and what constitutes a 'nutritional purpose' and/or a 'health effect'.</p>	<p>AFGC, brooke-taylor, Care A2+, Noumi</p>	<p>See Section 1.3.1.1 of this Report in terms of the definition of 'nutritive substance'.</p> <p>Applications seeking permission to use a substance as a nutritive substance must state the nutritional purpose for the use of that substance in the relevant food and provide evidence to demonstrate that the use can contribute to that purpose or achieve the intended outcome.</p> <p>In this Application, that statement and evidence was provided. As explained above, FSANZ's assessment was that the intended use in that context constitutes use as a nutritive substance. FSANZ considers the outcomes of the assessment on the anti-infective benefit discussed in SD1 and closer alignment with hLf levels in breastmilk sufficient to demonstrate a 'nutritional purpose' to bLf when concentrated, refined and added to IFP to the proposed amounts.</p>

Issue	Raised by	FSANZ response
<p>FSANZ has identified a 'health effect' for bLf in its assessment. This is a therapeutic effect, not a nutritional purpose and thus should not be classified as a 'nutritive substance'.</p>	<p>brooke-taylor</p>	<p>No claims are permitted on infant formula products. Although the 'health effects' could be the subject of a health or therapeutic claim, it is the description of the impact (e.g. reduced risk of infection) that affects its regulatory status. Further, FSANZ considers that this assessment could not be used as the basis of a health claim, since assessment of any health claim was not part of FSANZ's consideration of this application.</p> <p>The use of bLf in this particular instance is to more closely align IFP with hLf levels and function in human breastmilk. FSANZ considers this to not be a therapeutic effect, rather it is a nutritive role in the normal growth and development of infants.</p> <p>FSANZ notes that, in its assessment, FSANZ had to have regard to the Ministerial Policy Guideline on <i>Regulation of Infant Formula Products</i>, including specific policy principle (j) of that guideline. Food Ministers set the latter to require consideration of the beneficial purpose for which substances are added to IFP and their effect, i.e.</p> <p>(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.</p> <p>This Report and SD1 have been amended to ensure clarity on this matter.</p>

Issue	Raised by	FSANZ response
<p>Support progression of <i>P1024 – Revision of the Regulation of Nutritive Substances and Novel Foods</i> to provide greater clarity on classification of foods requiring pre-market assessment. Submitters provided specific suggestions including:</p> <p>a) removal of ‘nutritive substance’ definition as part of P1024, to align with regulatory approaches in the European Union and United States; and/or</p> <p>b) FSANZ convene a workshop of stakeholders on definition of ‘nutritive substance’ and its application.</p>	<p>a2 Milk, AFGC, Dairy Australia, Fonterra, INC, NZFGC</p>	<p>FSANZ notes this comment and considers this out of scope for this Application.</p> <p>FSANZ was and is required to assess this Application in accordance with the FSANZ Act. This Application and assessment is not the vehicle to review Code provisions and regulatory approaches endorsed by the Food Ministers’ Meeting and relating to nutritive substances.</p>
Exclusive use permission		
<p>Support exclusive use permissions as a tool in the Code that is important for innovation and return on investment.</p>	<p>a2 Milk, Care A2+, Dairy Australia, INC, Nestlé, NZFGC, Synlait</p>	<p>FSANZ notes this comment.</p>

Issue	Raised by	FSANZ response
<p>Oppose granting an exclusive use permission on the basis that the Applicant has not demonstrated substantial investment in innovation of novel technology; and/or seek clarity on how exclusive use can be conferred if bLf is not novel, currently exists in the Australian market and the Applicant is not first to market.</p>	<p>AFGC, Beston, Care A2+, Dairy Australia, Fonterra, Nestlé, NSW FA, NZ FS</p>	<p>Any new ingredient or combination of ingredients purported to have a beneficial effect when added to IFP must undergo pre-market assessment to protect and promote the safety, growth and development of infants.</p> <p>Innovation within the infant formula sector has led to the development of a number of ingredients that do not clearly fit as either a novel food or a nutritive substance. In some instances, an ingredient may meet the definitions of both.⁵ This can occur when an ingredient is developed using a novel process, but is used as a nutritive substance in the final food. For regulatory clarity i.e. both implementation and enforcement purposes, the Code stipulates that a food cannot be regulated as both a novel food and a nutritive substance.⁶ To address this conundrum, FSANZ established the Advisory Committee on Novel Foods (ACNF) to consider and provide advice on regulating these types of ingredients. Typically, if an ingredient is a novel food used as a nutritive substance as defined in paragraph 1.1.2—12 of the Code, it will be regulated as a nutritive substance.</p> <p>The outcome of FSANZ’s deliberations and the granting of a limited exclusive use period is not considered to be precedent setting for the broader food supply as the decision specifically relates to the addition of bLf to IFP only and for an intended nutritional purpose. It will not be extrapolated to use in general foods.</p> <p>FSANZ is of the view that the investment in a new ingredient justifies a ‘first to market advantage’ in the specific food category of the</p>

⁵ Definitions in Standards 1.1.2—8 and 1.1.2—12.

⁶ Novel foods are regulated by Standard 1.5.1 and Schedule 25, and nutritive substances by Part 2.9 and Schedules 17 and 29.

Issue	Raised by	FSANZ response
		<p>applicant's specific brand of nutritive substance, in this instance IFP. In this regard, a precedent was set in March 2021 onwards with gazettal of Applications A1155, A1190 and A1233.</p> <p>Furthermore, the Applicant has provided evidence of their investment in preparing this Application. This included research and expenditure on ingredient processes, development of patented technology, manufacturing capital expenditure and trials, and conducting sensory, shelf-life and safety trials. Much of this was confidential commercial information (CCI) and was critical in informing FSANZ's assessment. The Applicant also invested financial resources in the preparation of this Application. Therefore, FSANZ considers it appropriate to grant a limited conditional exclusive use permission for the Applicant's bLf to be added to IFP in this instance.</p>
<p>Seek clarity on mechanism in Code by which an exclusive use permission can be conferred on a nutritive substance.</p>	<p>Fonterra</p>	<p>Historically, the condition of exclusivity was introduced into the Code at the request of the Food Ministers. At the time, it was requested that FSANZ consider exclusivity of use for novel foods in Standard 1.5.1 and to limit the period of exclusive permissions for up to 15 months, after which any exclusive permissions revert to a generic permission at the expiration of the approved period of exclusivity. Food Ministers endorsed exclusivity for the former as part of Proposal P305, and extended the permission to nutritive substances under Application A1155.</p> <p>The FSANZ Act allows for FSANZ to provide a limited conditional permission to a particular brand, where FSANZ has adopted a policy position that such limitation periods apply for a maximum of 15 months. Exclusive permissions are currently restricted to novel foods and nutritive substances. Where patents on the final ingredient are in place, exclusive use is redundant, for example GM foods.</p>

Issue	Raised by	FSANZ response
		Further information is available on the FSANZ website. ⁷
<p>Exclusivity is inconsistent with the specific policy principles for composition that state that composition should strive to achieve as closely as possible the growth and development of breastfed infants. Exclusivity reduces availability of a potentially beneficial substance to the market at the expense of commercial outcomes.</p>	Vic	<p>As discussed in this Report, the Ministerial Policy Guideline on <i>Regulation of Infant Formula Products</i> sets out that composition of infant formula must be safe, suitable for the intended use and strive to achieve normal growth and development compared to a healthy full term exclusively breastfed infant – as measured by appropriate physiological, biochemical and/or functional effects.</p> <p>FSANZ’s assessment of the stated beneficial effects is for the purpose of the requested voluntary compositional permission. FSANZ’s first order priority was to ensure there are no public health and safety risks in accordance with subsection 18(1) of the FSANZ Act. In having regard to all high order policy principles, FSANZ considers that the strength, quality and type of evidence assessed in this Application is appropriate for voluntary compositional permission.</p> <p>FSANZ’s deliberations and the granting of a limited exclusive use period is a separate secondary consideration. The granting of an exclusive use permission does not preclude anyone else from applying for permission to add their bLf to IFP, including within the 15 month exclusive permission period.</p> <p>Further, the approved variation relates to an ingredient that IFP manufacturers may purchase. The variation does not apply any restrictions on who may purchase the Applicant’s bLf during the 15 month exclusive use period.</p>

⁷ [Exclusivity of use for novel foods and nutritive substances \(foodstandards.gov.au\)](http://www.foodstandards.gov.au)

Issue	Raised by	FSANZ response
<p>Concerns about enforceability of exclusivity when bLf already occurs in bovine milk-based IFP naturally.</p>	<p>NSW FA</p>	<p>Paragraph 2.9.1—5(1)(b) specifies that the maximum permitted amount of a nutritive substance listed in S29—5 Column 2 includes the sum of any naturally occurring and added amounts of the substance. Paragraph 2.9.1—5(2) specifies that the labelled amount of the substance in the nutrition information panel must also be the sum of naturally occurring and added amounts of the substance.</p> <p>Subparagraph 2.9.1—21(1)(a)(iii) also requires the average amount of any substance <i>used as a nutritive substance</i> permitted by the standard to be declared in the nutrition information statement (NIS) required by section 2.9.1—21. bLf would need to be declared in the NIS when it is voluntarily added to an IFP as a nutritive substance.</p>
<p>Seek clarity on whether the proposed exclusive use permission is limited to infant formula products only.</p>	<p>Vic</p>	<p>As discussed in detail above, the exclusive use permission granted under this Application will apply only to IFP.</p>
<p>Seek clarity on the granting of exclusivity and the circumstances under which <i>exclusive capturable commercial benefit</i> is conferred.</p>	<p>AFGC, INC, NZFGC</p>	<p>An exclusive use permission is usually only considered by FSANZ if an applicant expressly applies for it. Such an application would be a paid application on the basis that its approval would confer an exclusive capturable commercial benefit on the applicant.</p> <p>The application of the FSANZ Act provisions relating to the imposition of statutory charges under that Act on the basis of an exclusive capturable commercial benefit are out of the scope of this application.</p>

Issue	Raised by	FSANZ response
<p>Recommend FSANZ review the concept of exclusive use permissions and/or conduct stakeholder engagement on the application of exclusive use permissions.</p>	<p>AFGC, Fonterra, NZ FS</p>	<p>FSANZ notes this comment and considers this out of scope for this Application.</p>
<p>Specification</p>		
<p>Do not support the specification as drafted, stating it is:</p> <ul style="list-style-type: none"> a) overly specific to the Applicant's product and will limit other manufacturers entering the ANZ market with a compliant bLf product; and/or b) overly prescriptive and therefore inconsistent with regulatory best practice of presenting the minimum effective regulation, and inconsistent with FSANZ corporate plan; and/or c) misaligned with EU and China regulatory standards and is therefore inconsistent with 	<p>a2 Milk, AFGC, Beston, Dairy Australia, Fonterra, INC, NZFGC, NZ FS, Tatua</p>	<p>FSANZ has considered these comments and the specification has been amended accordingly.</p> <p>The Application Handbook requires an applicant to provide a detailed specification, if one is not already available from one of the published sources identified in Schedule 3. Typically, such specifications are based on the Applicant's proprietary manufacturing process. The Applicant provided a detailed specification in Table 2-8 of the Application. As noted in Section 2.4 of SD1 (at CFS), FSANZ considered the information provided in the Application in relation to parameters for a new specification in Schedule 3, and drafted the proposed specification contained in Attachment 1 of the CFS.</p> <p>After consideration of submissions and in consultation with the Applicant, FSANZ has reconsidered the specification and changed or removed some parameters, including to align the specifications more closely with overseas specifications (i.e. the specifications set by China and the EU).</p>

Issue	Raised by	FSANZ response
<p>international harmonisation; and/or</p> <p>d) recommend that FSANZ specification aligns with EU and China.</p>		<p>See responses below, Section 2.3.9 of this Report and Section 2.4 of the SD1 for further information.</p>
<p>FSANZ principles and reasoning for inclusion and exclusion parameters in draft specification are unclear.</p>	<p>NZFGC, INC</p>	<p>The responses in this Table, Section 2.3.9 of this Report and Section 2.4 of the SD1 provide detailed information on the approach taken by FSANZ to develop the specification, and subsequent amendments after considering submissions.</p>
<p>Support widening the specification to align with EU and China, provided that exclusivity of 15 months is granted for Synlait bLf.</p>	<p>Synlait</p>	<p>FSANZ notes this comment and acknowledges this approach ensures public health and safety is maintained while supporting the principle of minimum effective regulation and minimisation of technical barriers to trade.</p> <p>As noted above and detailed below, the specification has been amended to ensure greater alignment with China and the EU.</p> <p>Refer to Section 2.3.9 of this Report and Section 2.4 of the SD1 for further information.</p>
<p>Suggest several parameters are unnecessary, not included in EU or China specifications, and should be removed from the specification, including: fat, solubility, cadmium, mercury, melamine, aluminium, aflatoxin, nitrate and nitrite.</p>	<p>a2 Milk, Fonterra, INC, NZFGC, Tatura</p>	<p>The specification has been amended by removing the parameters for fat, melamine, aluminium, aflatoxin, nitrate and nitrite. This is to align with other overseas specifications (i.e. the specifications set by China and the EU). Parameters for solubility are retained and the limits for arsenic, cadmium and mercury have been amended to reflect the default values in S3—4 of the Code.</p>

Issue	Raised by	FSANZ response
		Refer to Section 2.3.9 of this Report and Section 2.4 of the SD1 for further information.
Suggest aflatoxin maximum amount is amended to ≤ 0.5 $\mu\text{g}/\text{kg}$ to better align with international regulations.	Morinaga	The specification has been amended by removing the parameters for aflatoxin. This is to align with other overseas specifications (i.e. the specifications set by China and the EU). Refer to Section 2.3.9 of this Report and Section 2.4 of the SD1 for further information.
Suggest that pH is reported in a 2% solution, consistent with regulation in the EU and China.	Fonterra, Morinaga, Tatua	The specification has been amended to report pH in a 2% solution. This is to align with other overseas specifications (i.e. the specifications set by China and the EU). Refer to Section 2.3.9 of this Report and Section 2.4 of the SD1 for further information.
Iron content of bLf is not a food safety issue and therefore should not be included in the specification.	Beston	FSANZ disagrees with this comment. The iron content, and therefore saturation, of bLf has an impact on the beneficial outcomes of bLf when used as a nutritive substance in IFP. If the bLf is fully saturated, it cannot bind and sequester iron from pathogens. Thus, iron content and saturation is a critical part of the specification.
Suggest the maximum iron content in the specification is increased to 35 mg/100 g, consistent with evidence on	a2 Milk, Dairy Australia, Fonterra, INC, Morinaga, NZ FS, NZFGC, Tatua	The specification has been amended from a maximum iron content of 15 mg/100 g to 35 mg/100 g. This is to align with other overseas specifications (i.e. the specifications set by China and the EU).

Issue	Raised by	FSANZ response
safety and international regulations.		Refer to Section 2.3.9 of this Report and Section 2.4 of the SD1 for further information.
Seek clarity on the iron content specified in the proposed amendment to Schedule 3. Will it impact on other lactoferrins added to IFP at the conclusion of the 15 month exclusivity period?	NSW FA	<p>As discussed above, the specification has been amended to allow a higher iron content of up to 35 mg/100 g. This is to align with other overseas specifications (i.e. the specifications set by China and the EU).</p> <p>This approach ensures public health and safety is maintained while supporting the principle of minimum effective regulation and minimisation of technical barriers to trade.</p> <p>Refer to Section 2.3.9 of this Report and Section 2.4 of the SD1 for further information.</p>
Inclusion of heavy metals in specification is inconsistent with other specifications in the Code, and/or that limits in Schedule 19 of the Code should be sufficient.	Beston, Dairy Australia	<p>As detailed above, the specification has been amended so that the values are comparable to those set internationally (i.e. primarily the specifications set by China and the EU).</p> <p>S3—4 of the Code sets default values for lead, arsenic, cadmium and mercury, if there is not already a value set in a specification. Thus all ingredients subject to Schedule 3 of the Code must meet a specification for these four parameters.</p> <p>The specification has been amended and the default limits for arsenic, cadmium and mercury in S3—4 of the Code apply. A more stringent lower limit is proposed for lead, compared to the value in S3—4, to align with the lower limit in the China specification.</p> <p>Therefore, it is not inconsistent to include specification values for heavy metals in a new specification for bLf.</p>

Issue	Raised by	FSANZ response
International stakeholders accept results of the annual Australian Milk Residue Analysis survey conducted by the Department of Agriculture, Fisheries and Forestry as verification of compliance with chemical residue limits, including for heavy metal.	Beston	FSANZ notes this comment.
The empirical formula presented in the draft specification is for Lactoferricin B, a derivative of bLf. Its inclusion in the specification is unnecessarily restrictive and should be removed.	Fonterra, Morinaga	The specification has been amended to remove the empirical formula. This has been replaced by a description of bLf in the specification, which FSANZ considers to be more appropriate than the inclusion of the empirical formula.
Suggest purity is represented as a “% of peak area” for consistency with other jurisdictions.	Fonterra	The specification has not been amended as the numerical value for % purity is consistent with the specifications set by China and the EU.
Suggest the CAS number is reviewed to ensure it is correct for bLf.	Fonterra	The specification has been amended to remove the CAS number. This has been replaced by a broader description of bLf in the specification which describes that the source is cow’s milk.

Issue	Raised by	FSANZ response
<p>If the draft specification is not amended, <i>Food Act 2014</i> s347 exemptions allowing export of bLf-containing IFP to certain overseas markets will need to be amended.</p>	<p>Fonterra</p>	<p>FSANZ notes this comment. As discussed above, the specification has been amended to ensure greater alignment with other overseas specifications (i.e. the specifications set by China and the EU).</p>
<p>Naturally occurring lactoferrin in cow's milk is largely denatured during processing and adding bLf at the dry-blend stage is the best way to ensure bLf provides a benefit when added to IFP as a nutritive substance.</p>	<p>Synlait</p>	<p>FSANZ notes this comment.</p>
<p>Clarification required as the draft specification on page 22 of the CFS states an iron maximum of <u>15 g</u>/100 g whereas the SD1 states <u>15 mg</u>/100 g.</p>	<p>AFGC, Fonterra, INC, NZ FS, NZFGC, Synlait</p>	<p>FSANZ notes this typographical error. The specification has been amended to ensure that mg/100 g are the units used to report the iron maximum.</p>
<p>SD1, Section 2.2.3, first paragraph:</p> <ul style="list-style-type: none"> Please note that bLf may also be used in liquid IFP or liquid concentrate. 	<p>Synlait</p>	<p>FSANZ agrees with these comments and has made subsequent amendments to SD1.</p>

Issue	Raised by	FSANZ response
<ul style="list-style-type: none"> The last word should be “bioactivity” rather than “bioavailability”. 		
Safety		
Support FSANZ assessment that bLf is safe to add to IFP.	Fonterra, Synlait	FSANZ notes this comment.
The proposed permission for bLf in IFP should be expanded to include food for people aged above 12 months old as it is low risk.	Morinaga	FSANZ notes this comment and considers this out of scope for this Application.
Agree with FSANZ recommendation for mandatory allergen declarations within the existing generic and specific labelling requirements for IFP.	NZ FS	FSANZ notes this comment.

Issue	Raised by	FSANZ response
<p>Raised concerns that:</p> <ul style="list-style-type: none"> a) infant formula products have an adverse effect on health b) bLf in IFP suppresses appetite and negatively impacts human lactoferrin c) bLf in IFP presents food safety risks. d) FSANZ should not be accepting industry research and ideology. 	BAA	<p>The dossier provided by the Applicant to support their request included both research generated 'in-house' and commissioned, together with independent data that is publicly available which FSANZ considers appropriate for application use.</p> <p>As detailed in this Report, FSANZ undertook a rigorous and independent assessment of the Application. FSANZ's decisions are based on the best available evidence, ensuring public health and safety are upheld. No evidence has been provided by the submitter to the contrary.</p>
Quality of evidence		
FSANZ should consider evidence beyond that provided by industry.	BAA	<p>As detailed above, FSANZ did consider evidence beyond that provided by industry.</p> <p>FSANZ conducted a comprehensive risk assessment according to internationally accepted methods and principles for the risk assessment of chemical substances in foods. The assessment included a literature review and identification of additional studies not provided by the Applicant, critical assessments of the studies provided</p>

Issue	Raised by	FSANZ response
		by the Applicant, and a comprehensive dietary intake assessment for Australian and New Zealand consumers.
<p>Plausible evidence from in vitro and animal studies is not sufficient to meet specific policy principle (j) of the <i>Regulation of Infant Formula Products</i> guideline and is not appropriate to inform Code changes affecting the vulnerable population of infants.</p>	Tas PHS	<p>FSANZ has applied consideration of the Ministerial Policy Guideline on <i>Regulation of Infant Formula Products</i> in this assessment, noting:</p> <ul style="list-style-type: none"> • The proposed addition at the indicated concentration is safe. • The proposed maximum permitted amount of bLf added to IFP is comparable to hLf present in human milk, which accords with the policy to align the composition of IFP to human breastmilk. • Evidence presented demonstrates biological and mechanistic plausibility of the health benefits and supports a link to the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. • FSANZ considers the evidence is appropriate for the purpose of compositional permission, noting the addition is safe and comparable to human milk. • The term 'plausible' (as used in the assessment reports) is a conclusion about 'causality' of the physiological, biochemical and/or functional effects to produce any favourable health outcome. Biological plausibility is a key component of establishing a relationship between a biological factor and a particular outcome. <p>FSANZ considered that the evidence in the studies presented with this Application were sufficient to meet the requirements listed above for the purpose of the requested voluntary compositional permission and</p>

Issue	Raised by	FSANZ response
		<p>would meet the requirements detailed in section (j) of the Ministerial Policy Guideline <i>Regulation of Infant Formula Products</i>. In having regard to all high order policy principles, FSANZ considers that the strength, quality and type of evidence assessed in this application is appropriate for a voluntary compositional permission.</p>
<p>Seek 5-year review of evidence on:</p> <p>a) beneficial outcomes of bLf as was requested for <i>A1155 – Addition of 2'-FL to infant Formula Products</i>; and/or</p> <p>b) impact of bLf on iron status, stating the number of cited studies was limited and that addition of bLf could potentially result in infant iron uptake above recommendations.</p>	<p>Tas PHS, Vic</p>	<p>FSANZ does not consider such a measure to be warranted in this case.</p> <p>FSANZ is satisfied that its assessment is robust and reflective of the best available evidence. There were no identified public health and safety concerns with the addition of bLf to IFP up to a maximum permitted amount of 40 mg/100 kJ. This amount is consistent with hLf levels in mature human milk. FSANZ is also satisfied that its assessment sufficiently substantiates a beneficial role in accordance with the Ministerial Policy Guideline <i>Regulation of Infant Formula Products</i>.</p> <p>FSANZ notes that Lf is an iron-binding protein (SD1 Section 2.2.1), however FSANZ found no evidence that bLf was likely to interact negatively with the bioavailability, storage or metabolism of other nutrients. Similarly, if bLf was to theoretically increase iron absorption in any capacity, intake of iron by infants in the first year would not exceed the level of iron toxicity due to the maximum permitted amount of iron allowable in IFP under the Code.</p>
<p>Suggest noting that several other RCTs investigated the effect of bLf on iron status and showed that bLf does not negatively impact iron status and may in fact</p>	<p>Synlait</p>	<p>FSANZ screened all randomised controlled trials (RCTs) provided in Section 3.2.1.2 of the Application against its independent research protocol.</p> <p>To assess the effect of consuming IFP with added bLf compared to consuming human milk on iron status, FSANZ's protocol, including</p>

Issue	Raised by	FSANZ response
<p>support a healthy iron status; these studies are outlined in Section 3.2.1.2 of the Application.</p>		<p>study selection criteria, was informed by scientific and clinical information (see Section 4.1.2 and Appendix 2 of the SD1). FSANZ's assessment described five studies provided in the Application, however, the other studies provided in Section 3.2.1.2 of the Application did not meet the inclusion criteria.</p> <p>FSANZ notes its assessment aimed to identify potential adverse effects on iron status using human milk-fed, healthy infant iron status as the reference. FSANZ considers its methodological approach to be aligned with this purpose and with the intent of the application.</p> <p>The research protocol is described in detail in the SD1.</p>
<p>Comparison of iron status of formula fed infants consuming bLf-fortified IFP with those of breastfed infants does not allow the drawing of conclusions on the effect of hLf and bLf on iron bioavailability. Suggest a more appropriate way of assessing the impact of bLf on nutrient bioavailability may be by evaluating studies that compare bLf-fortified formula with the same formula that is not fortified with bLf in formula fed infants.</p>	<p>Synlait</p>	<p>As discussed in this Report, the Ministerial Policy Guideline on <i>Regulation of Infant Formula Products</i> sets out that composition of infant formula must be safe, suitable for the intended use and strive to achieve normal growth and development compared to a healthy full term exclusively breastfed infant – as measured by appropriate physiological, biochemical and/or functional effects.</p> <p>In this instance, FSANZ's primary objective was to determine the effect (if any) of consuming IFP with added bLf compared to consuming human milk on nutrient bioavailability. Comparison with healthy breastfed (human milk-fed) infants serves as the most relevant comparison for detecting clinically relevant differences to 'normal' infant nutritional and health outcomes.</p> <p>The research protocol is described in detail in the SD1.</p>
<p>Acknowledging the inclusion criteria was quite restrictive, suggest FSANZ provide more</p>	<p>NZ FS</p>	<p>FSANZ agrees that the inclusion criteria based on the requirements in Section 3.6.2 A.3.1 (b) of the FSANZ Application Handbook resulted in a highly restrictive inclusion criteria. This primarily resulted from the</p>

Issue	Raised by	FSANZ response
<p>detailed discussion on the reasons the selected studies (Table 8 of SD1) did not meet the pre-specified inclusion criteria and any likely impact of these limitations on its assessment of whether bLf affects infant growth and development.</p>		<p>exclusion of studies using IFP with iron content different to that specified in the Code and/or bLf content different to that requested by the Application. The reasons for exclusion at this stage are captured in Table 7 and Appendix 2 of the SD1.</p> <p>In taking a pragmatic approach, noting there were no safety concerns and a demonstrated beneficial role, FSANZ completed a secondary narrative review of the best available evidence on the effect (if any) of consuming bLf on infant growth and development. The primary limitation of such a review is that a direct correlation cannot be established. However, despite these limitations in process, FSANZ is confident that its evidence-based conclusions that bLf at up to 1 g/L (equivalent to 40 mg/100 kJ), is unlikely to adversely affect infant growth and development.</p>
<p>Support FSANZ's conclusion that <i>in vitro</i> studies provide evidence for the bacteriostatic, bactericidal and antiviral effects, providing mechanistic evidence for bLf having a role in the reduction in risk of bacterial and viral infection but consider that 'consistent' may not be the best descriptor for the human studies evidence.</p>	<p>NZ FS</p>	<p>FSANZ agrees with this comment and has made the following amendment within this Report and the SD1, "FSANZ identified no human studies that could provide strong evidence in support of the proposed beneficial outcome. However, based on the few available studies, data presented therein are in agreement with a reduction in risk of gastrointestinal infection."</p>
<p>Optimal infant nutrition</p>		

Issue	Raised by	FSANZ response
Consider it is inaccurate to state that IFP may be safely used as a 'breastmilk substitute'.	BAA	FSANZ acknowledges that breastfeeding is the recommended way to feed infants. As infants are a vulnerable population group, a safe and nutritious substitute is necessary when breastfeeding is not possible. Any changes to the composition of infant formula products must be established as safe and suitable prior to being permitted.
Concern that availability and marketing of infant formula is negatively impacting breast feeding rates.	BAA	<p>The Code covers the labelling of infant formula products. The marketing and distribution of breastmilk substitutes for industry are overseen by two voluntary agreements:</p> <ul style="list-style-type: none"> • the Australian Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (the MAIF Agreement), and • the New Zealand Infant Nutrition Council Code of Practice for the Marketing of Infant Formula (CoPMIF). <p>These non-regulatory agreements specify restrictions for the marketing and distribution of breastmilk substitutes for industry, including restrictions on products being advertised or otherwise promoted to the public.</p>
Infants unable to receive breastmilk should have access to IFP developed based on the latest evidence.	AFGC, Nestlé, Synlait	FSANZ notes this comment. As infants are a vulnerable population group, a safe and nutritious substitute is necessary when breastfeeding is not possible. Any changes to the composition of infant formula products must be established as safe and suitable prior to being permitted.
Permitting voluntary addition of ingredients to IFP may allow industry to market their products	Tas PHS	As stated in Section 1.3.1.4 of this Report, the Code prohibits the use of nutrition content and health claims and certain representations on the label of an IFP (e.g. the use of specific words such as 'human milk

Issue	Raised by	FSANZ response
<p>as equivalent or superior to breastmilk and give consumers the perception that infant formula is superior to breastmilk, and thus undermine breastfeeding.</p>		<p>oligosaccharide'). Further, the Code prohibits information on IFP labels relating to the nutritional content of human milk (paragraph 2.9.1—24(1)(e)). These existing prohibitions aim to prevent misleading or deceptive conduct and will apply to IFP containing bLf.</p> <p>Commonwealth, state and territory, and New Zealand consumer protection legislation are in place to protect consumers from being misled about the products they purchase, including IFP.</p> <p>Marketing practices for IFP are controlled in Australia through the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (the MAIF Agreement), and in New Zealand through the INC Code of Practice for the Marketing of Infant Formula in New Zealand (and two other voluntary codes of practice).</p>
<p>Industry should be able to communicate the benefits of bLf in IFP on the label.</p>	<p>Care A2+</p>	<p>FSANZ notes this comment, see response above regarding prohibited representations.</p>
<p>Potential benefit to consumers of greater choice of IFP in the market is speculative and indicates greater focus on industry benefit than public health outcomes.</p>	<p>Tas PHS</p>	<p>Providing choice to consumers is one aspect of a cost-benefit analysis. As detailed in this Report, the use of bLf as proposed will not pose a health or safety risk for consumers and the composition of the product aligns with the intended purpose of that product.</p> <p>The proposed permission may provide potential beneficial health outcomes for infants. Consumers may therefore benefit from the choice of IFP containing the Applicant's bLf that become available.</p> <p>As the proposed permission is voluntary, industry are provided with product innovation opportunities and will use bLf in IFP only where they believe a net benefit exists for themselves.</p>

2.2 Risk assessment

FSANZ has assessed an Application from Synlait Milk Ltd. (the Applicant) to amend the Code to permit the voluntary addition of bLf as a nutritive substance in IFP.

The Applicant is proposing to add bLf to infant formula, follow-on formula and infant formula for special dietary use up to a maximum permitted amount of 40 mg/100 kJ, equivalent to ~ 1 g/L. The Application states the purpose for adding bLf to IFP is to more closely reflect the Lf content in human milk, and to provide a reduced risk of infection in formula-fed infants compared with those receiving standard IFP not fortified with bLf.

FSANZ has undertaken an assessment of the food technology aspects, safety, nutritional impact and beneficial role of the addition of bLf to IFP.

bLf is a protein naturally present at low levels in cow's milk. It shares 69% amino acid sequence homology with hLf, found in human milk. Information reviewed in the food technology assessment demonstrates that bLf is sufficiently characterised, and confirms its stability in IFP. Identity and purity specifications specifically related to bLf have been proposed for inclusion in Schedule 3 of the Code, with which bLf would have to comply.

The safety assessment concluded there are no toxicological safety concerns from the addition of bLf to IFP at the proposed maximum permitted amount.

bLf is subject to partial hydrolysis in the stomach and small intestine, but a proportion resists digestion and is excreted in the faeces. Some fragments produced by partial hydrolysis also resist further digestion and are excreted in the faeces. In addition, a small proportion of intact bLf and its fragments is absorbed into the systemic circulation and excreted via the urine.

bLf is of low acute toxicity, with no adverse effects observed following oral administration to rats up to 2000 mg/kg bw. It was not mutagenic *in vitro*. No adverse effects were observed in a 13-week oral gavage toxicity study in rats at doses up to 2000 mg/kg bw/day, the highest dose tested.

No adverse effects of bLf have been reported in multiple intervention studies in infants, including the highly vulnerable group of preterm and very low birth weight infants. bLf concentrations up to 1000 mg/L formula were tested in the studies in term infants while the doses tested in preterm and very low birth weight infants ranged from 100 – 300 mg/kg bw/day. These doses were estimated as being equivalent to bLf concentrations ranging from 370 – 3704 mg/L.

The first bLf-fortified IFP were released for sale overseas in 1986. FSANZ is not aware of any adverse events related to consumption of these products in markets where they are available. The Applicant has also indicated that its post-marketing surveillance overseas, and that of international formula brand owners it supplies, has not identified any complaints or adverse events related to the addition of bLf.

Based on the maximum permitted amount proposed by the Applicant, the estimated mean and 90th percentile (P90) intakes of bLf from infant formula and follow-on formula range between 0.59 and 1.8 g/day (equivalent to 70 – 270 mg/kg bw/day). These intakes are less than the estimated mean and P90 intakes of hLf from human milk of 0.7 to 5.0 g/day, and approximately 10 – 30-fold lower than the no observed adverse effect level of 2000 mg/kg bw/day from the 13-week toxicity study of bLf in rats.

bLf is derived from cow's milk which is a food allergen. Some individuals with cow's milk allergy have immunoglobulin E (IgE) antibodies to bLf indicating sensitisation, but the clinical significance of this has not been confirmed and bLf is not currently listed as a cow's milk allergen by the World Health Organization and International Union of Immunological Societies (WHO/IUIS). The limited available evidence however is insufficient to conclude that bLf does not pose a food allergy risk to consumers with cow's milk allergy.

No additional microbiological safety risks arise from addition of bLf to powdered IFP and its preparation and consumption beyond those encountered with IFP that is not supplemented with bLf.

Several double-blind, RCTs have investigated the potential for bLf to affect infant growth and development. Differences in weight gain between bLf and control formula groups were less than the clinically relevant threshold of 3 g/day. It is concluded that consumption of infant formula with added bLf, at up to 1 g/L (equivalent to 40 mg/100 kJ), is unlikely to adversely affect infant growth and development. Infant iron status, investigated in one of these RCTs, was unaffected by bLf addition to infant formula.

In terms of beneficial role in IFP, the weight of evidence suggests a plausible mechanism by which bLf can reduce the risk of bacterial and viral infection. bLf has been shown to reduce the severity and duration of infection in relevant animal infection models. FSANZ identified no human studies that could provide strong evidence in support of the proposed beneficial outcome. However, based on the few available studies, data presented therein are in agreement with a reduction in risk of gastrointestinal infection.

2.3 Risk management

Breastfeeding is the recommended way to feed infants. However, a safe and nutritious substitute for human milk is needed for infants when breastfeeding is not possible. As infants are a vulnerable population group, IFP are regulated by prescriptive provisions for composition and labelling. Any changes to the composition of these products must be established as safe prior to being permitted.

2.3.1 Risk management options

The risk management options available to FSANZ at this stage of the statutory assessment are to:

- reject the draft application that was the subject of public consultation, or
- approve that draft application, or
- amend then approve the draft application.

FSANZ had regard to the requirements of the FSANZ Act (see Section 2.5 below) in developing the proposed regulatory measure. For the reasons set out in this Report, FSANZ considers it appropriate to approve an amended version of the draft variation proposed following assessment. The approved draft variation, as amended, will permit the use of bLf as a nutritive substance in IFP subject to certain conditions.

Further details on the permission and associated conditions are provided below.

2.3.2 Lactoferrin as a nutritive substance in IFP

The Applicant's intended use of bLf in IFP is as a nutritive substance, and therefore a pre-market assessment and express permission in the Code is required for its use.

In considering the proposed permission, FSANZ noted that the intent of the Code is to provide a safe and nutritious substitute for human milk for infants who are not able to be breastfed. Given this, and in accordance with the Ministerial Policy Guideline on *Regulation of Infant Formula Products*⁸, IFP composition should aim as closely as possible for nutritional equivalence to human milk. While FSANZ acknowledges that breastfeeding is the recommended way to feed infants, the intent of Standard 2.9.1 is not to replace human milk but to provide a safe, nutritionally replete, functional alternative for those infants for whom breastfeeding is not possible.

To assess the suitability of the proposed compositional changes to the Code, FSANZ recognised the importance of demonstrating a link between physiological, biochemical or functional effects of the ingredient on outcomes for formula-fed infants, with appropriate evidence, and using human milk as the primary reference for determining the composition of IFP as per specific policy principles (d) - (h) of the *Regulation of Infant Formula Products* guideline.

Lf is a protein found in human colostrum and mature human milk. The Australian Infant Feeding Guidelines (NHMRC, 2012) and the background paper to the Healthy Eating Guidelines for New Zealand Babies and Toddlers (Ministry of Health, 2008) note Lf as being important for the health and development of infants due to its anti-infective benefits. FSANZ's independent assessment found that Lf has demonstrated bacteriostatic, bactericidal and anti-viral effects, which support the development of the neonatal immune system and help to reduce infection (SD1 Section 5.1). While Lf occurs naturally in both human milk (hLf) and mammalian milk, concentrations differ, with bLf in cow's milk for example occurring in much lower concentrations compared to those in human milk. FSANZ found that mature human milk has a mean Lf concentration of 1230-3390 mg/L, while prepared IFP based on cow's milk has 10-27 mg/L (SD1 Section 3.3.2.2).

While Lf is naturally occurring at low levels in cow's milk with a history of safe use in Australia and New Zealand, this Application sought to add higher amounts of bLf to IFP, which has been concentrated and refined through substantially different techniques and technology to those considered traditional, for the purpose of providing a nutritive benefit to the formula-fed infant.

Section 1.3.1.1 of this Report outlines the criteria for a substance to be used as a nutritive substance in relation to a food. Based on this criteria, and the other information provided in this Section, pre-market assessment for use as a nutritive substance was appropriate and required for bLf when used as stated in IFP. This was consistent with the FSANZ Act requirements and relevant Ministerial Policy Guidelines.

⁸ Ministerial Policy Guidelines are available for review here: www.foodregulation.gov.au

2.3.3 Public health and safety considerations of bLf in IFP

FSANZ's risk assessment at SD1 (Section 3.1.7) found that bLf in IFP was well tolerated with no adverse effects in intervention studies and toxicity studies and no microbiological safety concerns were found. The absence of potential adverse outcomes was supported by FSANZ's dietary intake assessment (SD1 Section 3.3). FSANZ also concluded that consumption of IFP with added bLf, at 1000 mg/L (~40 mg/100 kJ), was unlikely to adversely affect infant growth and development (SD1 Section 4.2).

FSANZ also noted that Lf is an iron-binding protein (SD1 Section 2.2.1), however FSANZ found no evidence that bLf was likely to interact negatively with the bioavailability, storage or metabolism of other nutrients. Similarly, if bLf was to theoretically increase iron absorption in any capacity, intake of iron by infants in the first year would not exceed the level of iron toxicity due to the maximum permitted amount of iron allowable in IFP under the Code.

FSANZ recognises that bLf is derived from cow's milk which is a food allergen. The allergenicity assessment concluded that there is evidence some individuals with cow's milk allergy have IgE antibodies to bLf, indicating sensitisation. This is addressed in Section 2.3.8.2 of this Report.

Based on FSANZ's independent safety assessments, and noting the widespread use of bLf in IFP internationally without any reported adverse effects (see Section 1.3.3), FSANZ concluded there were no additional public health and safety concerns with the addition of the Applicant's bLf to IFP as a nutritive substance up to a maximum permitted amount of 40 mg/100 kJ, aside from the possible allergen risk.

2.3.4 bLf and beneficial outcomes in IFP

A demonstrable health outcome in conjunction with bringing the composition of IFP closer to that of human milk was aligned with the definition of IFP in the Code and reflected the primary purpose of consumption in supporting the development of infants that are not breastfed. This also aligned with specific policy principle (j) of the *Regulation of Infant Formula Products* guideline which required that substances added to IFP must have a substantiated beneficial outcome in normal growth and development of infants, or a technological role (taking into account, where relevant, the levels of comparable substances in breastmilk). FSANZ considered these requirements in assessing each of the beneficial health outcomes of bLf stated in the Application.

Based on FSANZ's assessment of beneficial health outcomes and role in the normal growth and development, FSANZ concluded that the use of the Applicant's bLf in the manner proposed would have a beneficial outcome. That is, it would be bioavailable in infants and perform a similar nutritional function to hLf in meeting the stated purpose of reducing risk of infection in infants.

2.3.5 Maximum permitted amount of bLf in IFP and units of expression

The proposed maximum permitted amount of bLf was based on the safety, technical and beneficial health outcome assessments, including estimated dietary intakes and naturally occurring levels of hLf in human milk.

FSANZ recognised that the proposed maximum permitted amount of 40 mg/100 kJ (equivalent to 1109 mg/L) of bLf in IFP was lower than the concentration of hLf in human milk (1230-3390 mg/L). The proposed maximum permitted amount was, however, consistent with the highest tested amount that posed no observed adverse effects in term infants (1000 mg/L), and was within the range of highest levels tested with no observed adverse effects for the highly vulnerable group of preterm and very low birth weight infants (370-3704 mg/L). Further, FSANZ found that bLf up to the proposed maximum permitted amount of 40 mg/100 kJ could convey beneficial health outcomes (SD1 Sections 3-5), whilst adding only that which is necessary to achieve a health outcome and posing no concerns of adverse effects.

Dietary intake from other sources of bLf was also considered in FSANZ's assessment. bLf exists in the Australia and New Zealand food supply as a naturally occurring protein in dairy products, with a typical bLf concentration of 100 mg/L in cow's milk (SD1 Section 3.3.2.2). After gazettal, infants aged 9 months consuming the conservative mean of 707 g cow's milk and cow's milk equivalent from products such as yoghurt or cheese, and the P90 intake of bLf from IFP based on the maximum permitted amount of bLf, would consume approximately 1250 mg bLf per day (140 mg/kg bw/day) (SD1 Section 3.3.2.2). This is below the level of 2000 mg/kg bw/day which showed no adverse effects in toxicological studies. Permitting voluntary addition of bLf to IFP at the proposed maximum permitted amount of 40 mg/100 kJ is thus unlikely to produce adverse effects across the first year of life, while providing potential benefits to infants.

FSANZ must also have regard to consistency between domestic and international food standards when developing or varying a food standard. While the compositional requirements for IFP varied internationally, alignment with regulations such as those from the European Union (EU) were particularly relevant for the trade of products to and from Australia and New Zealand. Alignment with international regulations is outlined in Section 1.3.3 of this Report and the proposed maximum permitted amount of 40 mg/100 kJ (equivalent to 1109 mg/L) was commensurate with maximum permitted amounts in Singapore, China and the European Union (EU).

FSANZ concluded that there was no evidence of harm or safety concerns from the addition of the Applicant's bLf to IFP at the proposed maximum permitted amount of 40 mg/100 kJ and that this provided sufficient international harmonisation.

2.3.6 Minimum permitted amount of bLf in IFP

A minimum permitted amount was not requested in the Application and was not determined by FSANZ. FSANZ found that bLf may reduce the presence of potentially pathogenic microflora in both the formula and the gastrointestinal tract. It does not however appear to modulate the host microbiome. Due to individual variations in these three environments FSANZ could not establish a minimum value below which the reduction in pathogenic microflora would not occur. This is consistent with the permissions overseas.

2.3.7 Permitted form in IFP

The Code currently specifies the required form of each nutritive substance permitted for use in IFP (see the table to section S29—5 of the Code). Permitting the voluntary addition of bLf to IFP would require the required form of the bLf to also be specified.

In its assessment of this Application, FSANZ determined the Applicant's bLf was safe for voluntary addition to IFP up to the maximum permitted amount of 40 mg/100 kJ. Assessment of other forms of Lf was not in the scope of this assessment, and thus the proposed

permission will apply only to Lf from a bovine source. FSANZ has amended the table to section S29—5 to list 'Lactoferrin' in Column 1 and 'Bovine lactoferrin' in Column 2. The ingredient specification is discussed further in Section 2.3.9 of this Report.

The permission will not prevent submission or approval of future applications seeking permission to add lactoferrin from other sources to IFP.

2.3.8 Labelling

Subsection 2.9.1—5(2) qualifies the labelling requirements in Standard 1.2.1 for the purposes of nutritive substances used in IFP. This subsection states a label may include words or other indications to the effect that the product contains a substance that is listed in Column 1 or Column 2 of the table to section S29—5 only. As indicated above in Section 2.3.7 of this Report, FSANZ has listed 'Lactoferrin' and 'Bovine lactoferrin' in Columns 1 and 2 of that table, respectively.

2.3.8.1 Statement of ingredients

Standard 1.2.4 requires food for sale to be labelled with a statement of ingredients unless exempt. The label on a package of IFP must contain a statement of ingredients. Should manufacturers choose to add bLf to IFP, then this substance will have to be declared in the statement of ingredients.

Generic ingredient labelling provisions in section 1.2.4—4 require ingredients to be identified using a name by which they are commonly known, or a name that describes its true nature, or a generic ingredient name if one is specified in Schedule 10 *Generic names of ingredients and conditions for their use*. A generic ingredient name for bLf has not been specified.

2.3.8.2 Mandatory allergen declarations

As noted in Section 2.2 and 2.3.3 of this Report, there is evidence some individuals with cow's milk allergy have IgE antibodies to bLf, indicating sensitisation. Given bLf is an ingredient derived from milk, an IFP containing bLf will require a mandatory declaration for milk to be made in accordance with Division 3 of Standard 1.2.3.

For infant formula and follow-on formula, the term 'milk' will be the required name⁹ and will need to be declared in the statement of ingredients and in a summary statement in accordance with requirements in Division 3 of Standard 1.2.3.

For infant formula products for special dietary use, either the term 'milk' or another name by which the food is commonly known will need to be declared, but other declaration requirements (e.g. for formatting and location) in Division 3 will not apply (subsections 1.2.3—6(4) and (5) of Standard 1.2.3).

⁹ **Required name**, of a particular food, means the name declared by section 1.2.3—5 as the required name for that food for the purposes of Division 3 of Standard 1.2.3.

2.3.8.3 Mandatory nutrition information

Section 2.9.1—21 requires the declaration of nutrition information in a nutrition information statement (NIS) on the label of IFP. The NIS is a single statement and may be in the form of a table, as recommended in section S29—10 *Guidelines for Infant Formula Products*.

Subparagraph 2.9.1—21(1)(a)(iii) requires the average amount of any substance *used as a nutritive substance* permitted by the standard to be declared in the NIS.

bLf will need to be declared in the NIS when it is voluntarily added to an IFP.

As stated above, labelling provisions in subsection 2.9.1—5(2) related to bLf as a nutritive substance in IFP will also apply.

2.3.8.4 Prohibited representations

Paragraph 2.9.1—24(1)(f) states that, subject to subsection 2.9.1—14(2), the label on a package of IFP must not contain a reference to the presence of any nutrient or substance that may be *used as a nutritive substance*, except for a reference in a statement relating to lactose under subsection 2.9.1—14(6), a statement of ingredients or a declaration of nutrition information under section 2.9.1—21. Where bLf is added to an IFP, the label on the package of IFP will have to comply with this requirement.

2.3.8.5 Voluntary representations

Paragraph 1.2.7—4(b) of Standard 1.2.7 states that a nutrition content or health claim must not be made about an IFP. This prohibition will apply in relation to bLf where it is used in IFP as a nutritive substance.

2.3.9 Specification

Section 1.1.1—15 requires that a substance *used as a nutritive substance* must comply with any relevant specification set out in Schedule 3. There are no specifications for bLf in Schedule 3. Therefore, in the absence of an appropriate published specification, a new individual specification for bLf was required for addition to Schedule 3.

The Applicant provided their manufacturing specification and batch analysis results, as well as the China and EU specification. FSANZ assessed the information and developed a proposed specification for inclusion in Schedule 3 for the Call for Submissions (Attachment C). Submitters recommended closer consistency with other overseas specifications (i.e. the specifications set by China and the EU). FSANZ reviewed the proposed specifications and consulted with the Applicant. FSANZ determined that a broader specification provides greater international alignment and confers appropriate chemical composition, purity and stability to fulfil the intended nutritional purpose in IFP.

This approach ensured public health and safety is maintained while supporting the principle of minimum effective regulation and minimisation of technical barriers to trade. As a result, the specification parameters were amended to ensure closer consistency with other overseas product specifications (see SD1 and the revised specifications in Attachment A). The Applicant was advised of the amendments.

2.3.10 Exclusivity

An applicant may request an exclusive use permission to use and sell a food (including a nutritive substance) for a certain period of time to recognise the investment made in developing a novel food or nutritive substance and the need to achieve return on this investment, thereby supporting innovation. Further information is available on the FSANZ website.¹⁰

The Applicant requested an exclusive use permission and provided evidence of their investment in preparing this Application. This included research and expenditure on ingredient processes, development of patented technology, manufacturing capital expenditure and trials, and conducting sensory, shelf-life and safety trials. Much of this was confidential commercial information (CCI) and was critical in informing FSANZ's assessment. The Applicant also invested financial resources in the preparation of this Application.

For the reasons stated above, FSANZ determined that this request was justified and decided to provide the Applicant with a 15 month exclusive use permission for bLf used as a nutritive substance to be added to IFP, commencing on the date of gazettal of the draft variation. This means that, during that 15 month period, the permission for addition of bLf used as a nutritive substance in IFP will apply exclusively to bLf under the brand Synlait in accordance with the Code.

Once the 15 month period ends, the exclusive use permission will revert to a general permission and any brand of bLf may be added to IFP provided it does not exceed maximum permitted amounts (subject to any conditions imposed by the Code), thereby allowing all manufacturers to innovate and benefit from the changed permission.

The exclusive use permission in the Code does not and cannot prevent approval of second or subsequent applications, either within the exclusive use period or during the progression of an application, for the use of the same food or ingredient by other food companies, providing the application process is undertaken. The approved draft variation will not change this.

2.3.11 Risk management conclusion

Having considered the evidence and all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines¹¹, FSANZ has decided to approve a draft variation to the Code (see Attachment A).

The approved draft variation will permit the voluntary addition of bLf as a nutritive substance in IFP in accordance with the Code. Specifically, the approved draft variation will amend:

- the table to section S29—5 of the Code to permit bLf for use as a nutritive substance in IFP up to a maximum permitted amount of 40 mg/100 kJ;
- Schedule 3 to include identity and purity specifications for bLf with which bLf that is used as a nutritive substance in IFP would have to comply;

¹⁰ [Exclusivity of use for novel foods and nutritive substances \(foodstandards.gov.au\)](https://www.foodstandards.gov.au)

¹¹ [Policy guideline on infant formula products](#) and [Policy guideline on intent of Part 2.9 of the Food Standards Code - special purpose foods](#).

- Standard 2.9.1 and Schedule 29 to: provide that substances may be permitted for use as a nutritive substance in IFP subject to conditions; and set a condition that, for a limited period of 15 months from gazettal of the draft variation, only bLf under the brand Synlait may be used as a nutritive substance in IFP.

Existing labelling requirements in Standard 2.9.1 apply where relevant.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and applied a standard communication strategy to this Application. Subscribers and interested parties were notified about the public consultation period via the FSANZ Standards Notification Circular. A media release, FSANZ's social media channels and Food Standards News were also used to raise awareness in the community regarding the opportunity for comment.

A public consultation paper called for submissions on FSANZ's assessment and on a draft variation from 6 October to 10 November 2022. FSANZ received 19 submissions and one late submission. FSANZ had regard to all submissions received for this Application as part of its assessment.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. All comments are valued and contributed to the rigour of our assessment.

2.5 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ had regard to the following matters in section 29 of the FSANZ Act.

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Impact Analysis (OIA), formerly the Office of Best Practice Regulation (OBPR), granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for the Applications relating to voluntary addition of nutritive substances to foods (OBPR correspondence dated 16 April 2013, reference 14943). This standing exemption was provided as permitting a new nutritive substance is deregulatory and the use will be voluntary if the Application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, gave consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (i.e.

rejecting the Application). This analysis considers the costs and benefits of approving this Application, namely:

- permitting the addition of bLf as a nutritive substance in IFP; and
- granting a 15 month exclusive use period (from the date of gazettal) for the addition of bLf as a nutritive substance in IFP.

The consideration of the costs and benefits in this Section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the potential positives and negatives of moving away from the status quo by approving this Application.

2.5.1.2 Costs and benefits of permitting the proposed use of bLf

2.5.1.2.1 Consumers

FSANZ's risk assessment concluded there were no safety concerns from the addition of bLf to IFP at the proposed maximum permitted amount.

FSANZ considered that domestic consumers could benefit from increased variety of IFP for sale, and the potential beneficial health outcomes for infants provided by the draft variation.

The intent behind granting an exclusive use permission is to facilitate industry innovation by allowing applicants to achieve return on investment. This could come at the expense of consumers in the short term as they could potentially be paying a premium price if they choose to purchase IFP containing bLf due to lack of competition during the limited period of the exclusive use permission.

2.5.1.2.2 Industry

Due to the voluntary nature of the permission, industry will only use the nutritive substance where they believe a net benefit exists for them.

Permitting the use of bLf in IFP in Australia and New Zealand is consistent with a number of international permissions to use the substance in similar products, including China, Japan, the European Union, and the USA. Therefore, the approval of this nutritive substance in the Code may help some of Australia's and New Zealand's sales in international markets. There may, however, be competing imports from these countries into the domestic market.

Granting an exclusive use period could potentially create a monopoly and restrict trade temporarily during those 15 months. However, as explained in Section 2.3.10 above, the granting of an exclusive use permission does not preclude any other company from requesting the same permission. Therefore, the market will be open during those 15 months for any company willing to make an application. Given that the status quo is that bLf is not currently permitted for use in IFP, and the significant amount of time typically needed for reformulation of IFP, the 15 month exclusive use permission is unlikely to have a significant impact on competition. However, it does still represent a barrier to entry in terms of this specific market.

Due to the voluntary nature of the proposed permission, it is hard to estimate impact of the exclusive use permission on other bLf manufacturers. Given that there is no existing

permission for bLf as a nutritive substance in IFP, impact should be minimal. Long term, industry as a whole is likely to benefit, on balance, from a move away from the status quo.

2.5.1.2.3 Government

Permitting this substance may result in a small cost to government in terms of adding bLf to the current range of nutritive substances that are monitored for compliance.

2.5.1.2.4 Conclusions from cost benefit considerations

FSANZ's assessment at the Call for Submissions stage was that the direct and indirect benefits that would arise from permitting the use of bLf as a nutritive substance in IFP most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

2.5.1.3 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

2.5.1.4 Any relevant New Zealand standards

Relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.5.1.5 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

FSANZ completed a safety and risk assessment (SD1) which is summarised in Section 2.2 of this Report. In doing this, FSANZ considered the evidence of any public health and safety risk associated with the intake of bLf as well as bLf's potential beneficial outcomes to infants who are consuming IFP. FSANZ concluded there were no additional public health and safety concerns with the addition of bLf to IFP as a nutritive substance up to a maximum permitted amount of 40 mg/100 kJ, aside from the possible allergen risk.

2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Current labelling requirements outlined in Sections 1.3.1.4 and 2.3.8 of this Report will apply to IFP containing added bLf and provide information to enable consumers to make an

informed choice.

2.5.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements, including prohibited representations outlined in Sections 1.3.1.4 and 2.3.8 of this Report will apply to IFP containing added bLf which aim to prevent misleading or deceptive conduct.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

Using the risk analysis framework, FSANZ considered the best available evidence to reach its conclusions on the safety, technical and beneficial health outcomes of bLf in IFP.

- **the promotion of consistency between domestic and international food standards**

FSANZ considered the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry. bLf is permitted for addition to IFP equivalent products in many overseas jurisdictions. The permission will promote consistency between domestic and a number of international food standards.

- **the desirability of an efficient and internationally competitive food industry**

The permission supports an internationally competitive food industry (see Section 2.3.5 of this Report).

- **the promotion of fair trading in food**

No issues were identified for this Application relevant to this objective.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

FSANZ had regard to both high order and specific policy principles in relevant Ministerial Policy Guidelines. Two Ministerial Policy Guidelines specifically applied to this Application:

- Regulation of Infant Formula Products
- Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods.

Noting the assessment in SD1 and the assessment above of FSANZ Act requirements, FSANZ considered these Ministerial Policy Guidelines have been met.

3 References

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on bovine lactoferrin. EFSA Journal 2012;10(5):2701. [26 pp.]. doi:10.2903/j.efsa.2012.2701. www.efsa.europa.eu/efsajournal

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Ministry of Health. (2008). Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0–2): A background paper (4th Ed). [https://www.moh.govt.nz/notebook/nbbooks.nsf/0/1CB71808F8E129AFCC2574520008337D/\\$file/0-2-food-and-nutrition-guidelines-may08.pdf](https://www.moh.govt.nz/notebook/nbbooks.nsf/0/1CB71808F8E129AFCC2574520008337D/$file/0-2-food-and-nutrition-guidelines-may08.pdf)

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National Health and Medical Research Council [NHMRC]. (2012). Infant Feeding Guidelines: Information for health workers. <https://www.nhmrc.gov.au/about-us/publications/infant-feeding-guidelines-information-health-workers>

USA Food and Drug Administration [USFDA]. (2017). GRAS Notice No. GRN 000669. <https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=669&sort=GRNNo&order=DESC&startrow=1&type=basic&search=669>

Attachments

- A. Approved draft variation to the Australia New Zealand Food Standards Code
- B. Explanatory Statement
- C. Draft variation to the Australia New Zealand Food Standards Code (Call for Submissions)

Attachment A – Approved draft variation to the Australia New Zealand Food Standards Code



Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name and position title]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Standard 2.9.1—Infant formula products

[1] Paragraph 2.9.1—5(1)(b)

Repeal the paragraph, substitute:

- (b) the amount of the substance in the product (including any naturally-occurring amount) is no more than the corresponding amount listed in Column 4 of the table; and
- (c) it complies with any conditions listed in section S29—5A in relation to that substance.

Schedule 3—Identity and purity

[2] Subsection S3—2(2) (table)

Insert:

bovine lactoferrin

section S3—46

[3] After section S3—45

Insert:

S3—46 Specification for bovine lactoferrin

- (1) In this section, bovine lactoferrin is a protein derived from cow's milk and consisting of a single polypeptide chain of 689 amino acids.
- (2) For bovine lactoferrin, the specifications are the following:
 - (a) description—a pink to reddish brown coloured, free-flowing powder;
 - (b) protein (N x 6.38)—more than 93.0%;
 - (c) purity—more than 95.0%;
 - (d) moisture—less than 4.5 g/100 g;
 - (e) ash—not more than 1.5 g/100 g;
 - (f) iron—not more than 35 mg/100 g;
 - (g) pH (2% solution)—5.2 to 7.2;
 - (h) solubility transmittance (2% solution, 20°C)—transparent;

- (i) lead—not more than 1 mg/kg;
- (j) microbial limits:
 - (i) *Salmonella* spp.—absent in 25 g;
 - (ii) *Listeria monocytogenes*—absent in 25 g;
 - (iii) *Cronobacter* spp.—absent in 10 g.

Schedule 29—Special purpose foods

[4] Section S29—5 (table)

Insert:

Lactoferrin	Bovine lactoferrin	40 mg
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[5] After section S29—5

Insert:

S29—5A Infant formula products—conditions on use of permitted nutritive substances

- (1) A substance that is:
- (a) listed in Column 1 of the table to subsection (2); and
 - (b) in a permitted form listed in Column 2 of that table for that substance;
- must comply with any corresponding conditions specified in Column 3 of that table for that permitted form.
- (2) The table for this subsection is:

Conditions of use for permitted nutritive substances

<i>Column 1</i>	<i>Column 2</i>	<i>Column 3</i>
Substance	Permitted Form	Conditions of use
Lactoferrin	Bovine lactoferrin	1. During the exclusive use period, may only be sold under the brand Synlait for *use as a nutritive substance in an infant formula product. 2. For the purposes of condition 1 above, exclusive use period means the period commencing on the date of gazettal of the <i>Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation</i> and ending 15 months after that date.

Attachment B

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1253 which seeks to permit the addition of bovine lactoferrin (bLf) as a nutritive substance in infant formula products (IFP). The Application also sought a 15 month exclusive use permission for the Applicant's brand of bLf. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation - *Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation*.

Following consideration by the Food Ministers' Meeting, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by

the Food Ministers' Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation to the Code to:

- amend Schedule 29 and Standard 2.9.1 to permit the addition of bLf as a nutritive substance for use in IFP in accordance with the Code subject to certain conditions, including not exceeding the specified maximum amount and an exclusive use period of 15 months for the Applicant's brand of bLf; and
- insert prescribed specifications for bLf into Schedule 3, with which bLf would have to comply.

The approved draft variation includes consequential amendments to the Code as a result of the above amendments.

4. Documents incorporated by reference

The approved draft variation prepared by the Authority does not incorporate any documents by reference.

However, the approved draft variation would vary Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of the Code requires certain substances (such as substances used as nutritive substances) to comply with any relevant identity and purity specifications listed in Schedule 3. Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1253 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 6 October 2022 for a five-week consultation period.

The Office of Impact Analysis (OIA), formerly the Office of Best Practice Regulation (OBPR), granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for the Applications relating to voluntary addition of nutritive substances to foods (OBPR correspondence dated 16 April 2013, reference 14943). This standing exemption was provided as permitting the new nutritive substance is deregulatory and their use will be voluntary if the Application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human

rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

7.1 Item [1]

Item [1] of the Schedule to the approved draft variation amends subsection 2.9.1—5(1).

Subsection 2.9.1—5(1) provides for the use of nutritive substances in IFP. The subsection provides that a substance listed in Column 1 of the table to section S29—5 may be used as a nutritive substance in an IFP only if the following two conditions are met:

- (a) it is in a permitted form listed in Column 2 of the table; and
- (b) the amount of the substance in the product (including any naturally-occurring amount) is no more than the corresponding amount listed in Column 4 of the table.

In particular, **item [1]** substitutes existing paragraph 2.9.1—5(1)(b), which is currently the end of the subsection, with a new version of the paragraph ending with ‘; and’ which allows for the insertion of new paragraph 2.9.1—5(1)(c).

New paragraph 2.9.1—5(1)(c) sets out an additional condition which a substance listed in Column 1 of the table to section S29—5 must meet to be able to be used as a nutritive substance in an IFP—the substance complies with any conditions listed in section S29—5A in relation to that substance.

7.2 Items [2] and [3]

Items [2] and **[3]** of the Schedule to the approved draft variation amends Schedule 3.

Schedule 3 contains specifications for the purposes of section 1.1.1—15 of the Code. Section 1.1.1—15 requires certain substances, e.g. substances used as nutritive substances, to comply with any relevant identity and purity specifications listed in Schedule 3. Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)).

Item [2] amends the table to subsection S3—2(2) by inserting, in alphabetical order, a new entry for ‘bovine lactoferrin’ and a corresponding reference to new section S3—46 (see **item [3]** below).

Item [3] inserts, in numerical order, new section S3—46 into Schedule 3. The new section sets out a specification for the substance ‘bovine lactoferrin’, which contains identity and purity specifications for that substance.

7.3 Items [4] and [5]

Items [4] and **[5]** of the Schedule to the approved draft variation amend Schedule 29.

Item [4] amends the table to section S29—5 by inserting, in alphabetical order, a new entry for bLf into the table as follows:

Column 1 – ‘Lactoferrin’ as the substance;

Column 2 – ‘Bovine lactoferrin’ as the permitted form of the substance; and

Column 4 – ‘40 mg’ as the maximum amount of the substance in an IFP (per 100 kJ).

Item [5] inserts new section S29—5A into Schedule 29. The new section sets out the conditions of use of permitted nutritive substances in IFP.

Subsection S29—5A(1) refers to the table to subsection S29—5A(2) and provides that a substance that is:

- listed in Column 1 of the table to subsection (2); and
- in a permitted form listed in Column 2 of that table for that substance;

must comply with any corresponding conditions specified in Column 3 of that table for that permitted form.

Subsection S29—5A(2) sets out a table headed ‘Conditions of use for permitted nutritive substances’. The table has three Columns listing the substance, the permitted form of the substance, and conditions of use for the permitted form of the substance respectively.

‘Lactoferrin’ is listed as the substance in Column 1.

‘Bovine lactoferrin’ is listed as permitted form of the substance in Column 2.

The following two conditions (related to an exclusive use permission) are listed in Column 3:

1. During the exclusive use period, bLf may only be sold under the brand Synlait for use as a nutritive substance in an IFP.
2. For the purposes of condition 1 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation* and ending 15 months after that date.

The effect of the approved draft variation is to permit the use of bLf as a nutritive substance in IFP in accordance with the Code.

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (Call for Submissions)



Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name and position title]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Standard 2.9.1—Infant formula products

[1] Paragraph 2.9.1—5(1)(b)

Repeal the paragraph, substitute:

- (b) the amount of the substance in the product (including any naturally-occurring amount) is no more than the corresponding amount listed in Column 4 of the table; and
- (c) it complies with any conditions listed in section S29—5A in relation to that substance.

Schedule 3—Identity and purity

[2] Subsection S3—2(2) (table)

Insert:

bovine lactoferrin

section S3—46

[3] After section S3—45

Insert:

S3—46 Specification for bovine lactoferrin

For bovine lactoferrin, the specifications are the following:

- (a) chemical name—bovine lactoferrin;
- (b) chemical formula— $C_{141}H_{224}N_{46}O_{29}S_3$;
- (c) CAS number—146897-68-9;
- (d) description—pink to reddish brown coloured, free-flowing powder;
- (e) protein (N x 6.38)—more than 95.0%;
- (f) purity (on a protein basis)—more than 95.0%;
- (g) moisture—less than 4.5g/100g;
- (h) ash—not more than 1.3g/100g;
- (i) fat—not more than 1g/100g;
- (j) iron—not more than 15g/100g;

- (k) pH (10% solution)—5.2 to 7.2;
- (l) solubility transmittance (2% solution, 20°C)—transparent;
- (m) lead—not more than 0.02 mg/kg;
- (n) cadmium—not more than 0.1 mg/kg;
- (o) mercury—not more than 0.1 mg/kg;
- (p) arsenic—not more than 0.02 mg/kg;
- (q) melamine—not detected;
- (r) aluminium—not more than 4.8 mg/kg;
- (s) aflatoxin M1—not more than 0.05 µg/kg;
- (t) nitrate—not more than 50 mg/kg;
- (u) nitrite—not more than 2.0 mg/kg;
- (v) microbial limits:
 - (i) *Salmonella* spp—absent in 25 g;
 - (ii) *Listeria monocytogenes*—absent in 25 g;
 - (iii) *Cronobacter* spp—absent in 10 g.

Schedule 29—Special purpose foods

[4] Section S29—5 (table)

Insert:

Lactoferrin	Bovine lactoferrin	40 mg
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[5] After section S29—5

Insert:

S29—5A Infant formula products—conditions on use of permitted nutritive substances

- (2) A substance that is:
 - (c) listed in Column 1 of the table to subsection (2); and
 - (d) in a permitted form listed in Column 2 of that table for that substance;
 must comply with any corresponding conditions specified in Column 3 of that table for that permitted form.
- (2) The table for this subsection is:

Conditions of use for permitted nutritive substances

Column 1	Column 2	Column 3
Substance	Permitted Form	Conditions of use
1 Lactoferrin	Bovine lactoferrin	<ol style="list-style-type: none"> 3. During the exclusive use period, may only be sold under the brand Synlait for *use as a nutritive substance in an infant formula product. 4. For the purposes of condition 1 above, exclusive use period means the period commencing on the date of gazettal of the <i>Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation</i> and ending 15 months after that date.