

**6 October 2022**  
**216-22**

## **Call for submissions – Application A1253**

### **Bovine lactoferrin in infant formula products**

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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 and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

All submissions on Applications and Proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct Application or Proposal number and name. Electronic submissions can be made by emailing your submission to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au). FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 10 November 2022**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making a submission or Application and Proposal processes can be sent to

[standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Submissions in hard copy may be sent to the following addresses:

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## **Supporting documents**

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) has 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 to infant formula products (IFP) up to a maximum permitted amount of 40 mg/100 kJ. The Applicant has also requested an exclusive use permission for their brand of bovine lactoferrin 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 mammal 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 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's risk and technical assessment identified no 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 health outcomes in accordance with relevant Ministerial Policy Guidelines 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 level of 40 mg/100 kJ brings IFP closer to levels in mature human milk, aligns with international regulations and adds only that which is necessary to achieve a potential health effect.

FSANZ has therefore prepared a draft variation to the Code which, if approved, would amend the table to section S29—5 of the Code to list bLf as a nutritive substance permitted for use in IFP up to a maximum permitted amount of 40 mg/100 kJ. The draft variation would also amend Schedule 3 to include identity and purity specifications for bLf with which bLf would have to comply. The draft variation would also amend Standard 2.9.1 and Schedule 29 to require nutritive substances listed in the table to section S29—5, e.g. bLf, to comply with any conditions listed in section S29—5A in relation to the substance concerned. In the case of bLf, the only condition proposed is an exclusive use permission whereby bLf under the brand Synlait could only be sold for use as a nutritive substance in an IFP, for a period of 15 months after gazettal of the draft variation (if approved).

The proposed permission would be subject to existing labelling requirements. FSANZ now seeks comments on the draft variation (Attachment A).

# 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 to 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 reports 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 Application states that differences in structure result in only small differences in cellular uptake and functionality, and bLf has been shown to provide benefits similar to those provided by hLf. The Application states that bLf has a history of safe consumption by humans and claims bLf can reduce the risk of infections in infants without potential adverse effects.

If approved, 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 standard

### 1.3.1 Australia and New Zealand

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

#### 1.3.1.1 *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 draft variation proposes to insert a specification specifically for bLf into Schedule 3 with which, if the draft variation is approved, bLf would have to comply.

#### 1.3.1.2 *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 was *used as a nutritive substance* (as defined in section 1.1.2—12). bLf would be a substance *used as a nutritive substance* for the purposes of the Code because its proposed addition to IFP is intended to achieve specific nutritional purposes.

Therefore, if approved, express permission for bLf to be *used as a nutritive substance* is required in accordance with Standard 2.9.1 (i.e. be listed in the table to section S29—5; and be in a permitted form at up to the maximum amount per 100 kJ specified in that table).

### **1.3.1.3 Infant formula products**

The composition of IFP is regulated in Standard 2.9.1 and Schedule 29. This standard and associated schedule sets out specific compositional and labelling requirements for the following IFP:

- infant formula (for infants aged 0 to <12 months);
- follow-on formula (for infants aged from 6 to <12 months); and
- infant formula products for special dietary use (for pre-term infants and infants aged 0 to <12 months with special dietary needs).

In particular, section 2.9.1—5 states 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:

- (a) it is in a permitted form listed in Column 2 of the 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 the table.

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

Therefore, express permission for bLf to be *used as a nutritive substance* in IFP in accordance with the Code is required before bLf can be used as proposed.

### **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 sale<sup>1</sup>.

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.

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<sup>1</sup> 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.

### 1.3.1.5 Key Definitions

**infant** means a person under the age of 12 months.

**infant formula product** means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.

**infant formula** means an infant formula product that is represented as a breast-milk substitute for infants; and satisfies by itself the nutritional requirements of infants under the age of four to six months.

**follow-on formula** means an infant formula product that is represented as either a breast-milk substitute or replacement for infant formula; and is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of six months.

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

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

- (a) any substance that is identified in this Code as one that may be used as a nutritive substance; and
- (b) a vitamin or a mineral; and
- (c) any substance (other than an inulin-type fructan, a galacto-oligosaccharide or a substance normally consumed as a food) that has been concentrated, refined or synthesised, to achieve a nutritional purpose when added to a food.

### 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<sup>2</sup>.

### 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

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<sup>2</sup> Currently under review by CCNFSDU. For further information, search on the [Codex Alimentarius website](#).



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 is being assessed under the General Procedure.

# 2 Summary of the assessment

## 2.1 Risk assessment

FSANZ has undertaken an assessment of the food technology aspects, safety, nutritional impact and beneficial health effects of the addition of bLf to IFP. A summary of this assessment is provided below.

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 concentrations. 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 and to the best of FSANZ's knowledge there have been no 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 90<sup>th</sup> percentile (P90) intakes of bLf from infant formula and follow-on formula range between 0.59 and 1.8 g/day (equal 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 major 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 Organisation 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 infant formula products and its preparation and consumption beyond those encountered with IFP that is not supplemented with bLf.

Several double-blind, randomised, controlled trials (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 effects, 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. The few relevant human studies provided weak but consistent support for the proposed beneficial effect.

## **2.2 Risk management**

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. Before a change in the composition of IFP is permitted, there must be evidence that the change would not pose a risk to the health and safety of consumers of these products, in this case, infants.

### **2.2.1 Risk management options**

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

For the reasons set out in this report, FSANZ decided to prepare a draft variation to the Code to permit the use of bLf as a nutritive substance in IFP, subject to certain conditions, if approved, the proposed permission would have to be exercised in accordance with the Code.

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

### **2.2.2 Lactoferrin as a nutritive substance in IFP**

In considering the proposed permission, FSANZ notes 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 Guidelines<sup>3</sup>, 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 compositional changes to the Code, FSANZ recognises the importance of demonstrating a link between physiological, biochemical or functional effects of the proposed ingredient to specific health outcomes for formula-fed infants, with appropriate evidence, and to use 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.

Lactoferrin (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 prevent 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 is seeking to add higher levels of bLf to IFP, which has been concentrated and refined through substantially different techniques and technology to those considered traditional. Therefore, FSANZ has determined that, given the intention is for use as a nutritive substance, pre-market assessment is required. This is consistent with the FSANZ Act requirements and relevant Ministerial Policy Guidelines.

### **2.2.3 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 is supported by FSANZ's

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<sup>3</sup> Ministerial Policy Guidelines are available for review here: [www.foodregulation.gov.au](http://www.foodregulation.gov.au)

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), is unlikely to adversely affect infant growth and development (SD1 Section 4.2).

FSANZ also notes that Lf is an iron-binding protein (SD1 Section 2.2.1), however FSANZ found no evidence that bLf is 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 levels of iron allowable in IFP under the Code.

Given the widespread use of bLf in IFP internationally (see Section 1.3.3) and FSANZ's independent safety assessment outcomes discussed above, FSANZ concludes there are no public health and safety concerns from the addition of bLf to IFP at the proposed concentrations.

#### **2.2.4 bLf and beneficial health effects in IFP**

A demonstrable health effect in conjunction with bringing the composition of IFP closer to that of human milk is aligned with the definition of IFP in the Code (see Section 1.3.1.5) and reflects the primary purpose of consumption in supporting the development of infants that cannot be breastfed. This also aligns with specific policy principle (j) of the *Regulation of Infant Formula Products* guideline which requires that substances added to IFP must have a substantiated beneficial effect in normal growth and development of infants, or a technological role. FSANZ has considered these requirements in assessing each of the beneficial health effects of bLf stated in the Application.

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

#### **2.2.5 Maximum permitted amount of bLf in IFP and units of expression**

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

FSANZ recognises that the proposed maximum permitted amount of 40 mg/100 kJ (equivalent to around 1109 mg/L) of bLf in IFP is lower than the concentration of hLf in human milk (1230-3390 mg/L). The proposed maximum permitted amount is however consistent with the highest tested amount posing no observed adverse effects in term infants (1000 mg/L), and 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 can convey beneficial health effects (SD1 Sections 3-5), thereby adding only that which is necessary to achieve a health effect while posing no concerns of adverse effects.

Dietary intake from other sources of bLf has also been 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). If the proposed permission is approved, 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, will 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 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 vary internationally, alignment with regulations such as those from the European Union (EU) are particularly relevant for the trade of products to and from Australia and New Zealand. Alignment with international regulations has been outlined in Section 1.3.3 of this report and the proposed maximum permitted amount of 40 mg/100 kJ (equivalent to around 1109 mg/L) is commensurate with maximum permitted amounts in Singapore, China and the European Union (EU).

FSANZ concludes that there is no evidence of harm or safety concerns from the addition of bLf to IFP at the proposed maximum permitted amount of 40 mg/100 kJ and that this provides sufficient international harmonisation.

#### **2.2.6 Minimum permitted amount of bLf in IFP**

A minimum permitted amount was not requested in the Application and has not been determined by FSANZ. FSANZ considers that ingredients which are intended to modulate gut microflora may result in variable outcomes in individuals due to the unique microbial ecology of individuals and a variety of host and environmental factors. For these reasons setting a minimum permitted amount is not an appropriate approach. This is consistent with the permissions in China, the EU and Singapore.

#### **2.2.7 Permitted form in IFP**

The table to section S29—5 of the Code specifies the permitted form of nutritive substances which would be permitted for addition to IFP. Permitting the voluntary addition of bLf to IFP as proposed requires this table to be amended.

In its assessment of this Application, FSANZ has determined bLf is 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 would apply only to Lf from a bovine source. FSANZ proposes to amend 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 2.2.9 of this report.

If approved, the proposed permission would not prevent submission or approval of future applications seeking permission to add Lf from other sources to IFP.

#### **2.2.8 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 2.2.7 of this report, FSANZ is proposing to list 'Lactoferrin' and 'Bovine lactoferrin' in Columns 1 and 2 of that table, respectively.

### **2.2.8.1 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 would 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.

### **2.2.8.2 Mandatory allergen declarations**

As noted in Section 2.1 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 would 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' would be the required name<sup>4</sup> and would 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 would need to be declared, but other declaration requirements (e.g. for formatting and location) in Division 3 would not apply (subsections 1.2.3—6(4) and (5) of Standard 1.2.3).

### **2.2.8.3 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 would 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 would also apply.

### **2.2.8.4 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 would have to comply with this requirement.

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<sup>4</sup> **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.

### **2.2.8.5 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 would apply in relation to bLf where it is used in IFP as a nutritive substance.

### **2.2.9 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 would be required for addition to Schedule 3.

The Applicant provided their manufacturing specification and batch analysis results. FSANZ assessed the information and developed a proposed specification for inclusion in Schedule 3. The proposed specification parameters are shown in Table 1 of SD1. This specification is included in the draft variation at Attachment A. While the specifications are based on the parameters provided in the Application, FSANZ is of the view that these are sufficiently generic to allow for future innovation.

### **2.2.10 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 ingredient or nutritive substance and the need to achieve return on this investment, thereby supporting innovation.

The Applicant has requested an exclusive use permission for bLf for a period of 15 months on the basis that they have invested significantly in the technology development and safety studies.

FSANZ is proposing to provide the Applicant with a 15 month exclusive use permission for bLf commencing on the date of gazettal of the draft variation (if approved).

If the draft variation is approved, this means that, during that 15 month period, the permission would apply exclusively to that substance under the brand 'Synlait' in accordance with the Code.

Once the 15 month period ends, the exclusive use permission would revert to a general permission, meaning that the permission would apply to all brands of bLf in accordance with the Code.

An exclusive use permission does not, and cannot, prevent approval of second or subsequent applications under the Code, 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.

### **2.2.11 Risk management conclusion**

Having considered all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines, FSANZ has prepared a draft variation to the Code to permit the proposed voluntary addition of bLf to IFP.

FSANZ proposes the changes to the Code based on the safety data for both chronic and

acute bLf intake, consideration of the proposed health benefit and the need to have IFP that are a safe, nutritionally replete options that serves as the principal liquid source of nourishment for infants that are not able to benefit from human milk.

If the draft variation is approved, the addition of bLf to IFP would be subject to relevant requirements and conditions in the Code, which include the following:

- It may be voluntarily added up to a maximum level of 40 mg/100 kJ, as consumed.
- Existing generic and specific labelling requirements for IFP as set by the Code would apply.
- Schedule 3 of the Code would set specific identity and purity specifications for bLf, with which bLf would have to comply.
- An exclusive use permission for bLf would apply for a period of 15 months, linked to the Applicant's brand name 'Synlait', commencing on the date of gazettal of the draft variation (if approved).

## **2.3 Risk communication**

### **2.3.1 Consultation**

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

FSANZ developed and applied a standard communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release, through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received on this call for submissions.

The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the assessment.

### **2.3.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards and amending the Code to permit the voluntary addition of bLf to IFP as proposed is unlikely to have a significant effect on international trade as this substance is already permitted in similar products overseas. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## **2.4 FSANZ Act assessment requirements**

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



## **2.4.1 Section 29**

### **2.4.1.1 Consideration of costs and benefits**

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.

FSANZ, however, has given 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 is 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 permitting the proposed addition of bLf as a nutritive substance in IFP.

The consideration of the costs and benefits in this section is 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 seeks to highlight the potential positives and negatives of moving away from the status quo by permitting the proposed use of this nutritive substance.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from this Call for Submissions, may result in FSANZ arriving at a different conclusion.

### **2.4.1.2 Costs and benefits of permitting the proposed use of bLf**

#### **2.4.1.2.1 Consumers**

Consumers would potentially benefit from an increase in choice of IFP in the market.

#### **2.4.1.2.2 Industry**

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

Permitting the proposed 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.

#### **2.4.1.2.3 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.

#### **2.4.1.2.4 Conclusions from cost benefit considerations**

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the proposed use of bLf as a nutritive substance in IFP most likely outweigh the associated costs.

#### **2.4.1.3 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.

#### **2.4.1.3 Any relevant New Zealand standards**

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

#### **2.4.1.4 Any other relevant matters**

Other relevant matters are considered below.

### **2.4.2 Subsection 18(1)**

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

#### **2.4.2.1 Protection of public health and safety**

FSANZ completed a safety and risk assessment (SD1) which is summarised in Section 2.1 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 health effects to infants who are consuming IFP. The assessment concluded that there are no safety concerns with the addition of bLf to IFP as a nutritive substance up to the proposed level of 40 mg/100 kJ.

#### **2.4.2.2 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 2.2.8 of this report would apply to IFP containing added bLf and provide information to enable consumers to make an informed choice.

#### **2.4.2.3 The prevention of misleading or deceptive conduct**

Current labelling requirements, including prohibited representations outlined in Section 1.3.1.4 and 2.2.8 of this report would apply to IFP containing added bLf which aim to prevent misleading or deceptive conduct.

### **2.4.3 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 has 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 proposed permission would promote consistency between domestic and a number of international food standards.

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

The proposed permission would support an internationally competitive food industry (see Section 2.2.5 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<sup>5</sup>**

FSANZ has 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 considers these Policy Guidelines would be met by the proposed permission, if approved.

### **3 Draft variation**

The draft variation to the Code is at Attachment A and, if approved, is intended to take effect on gazettal.

A draft 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.

### **4 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.

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<sup>5</sup> Formerly known as the Australia and New Zealand Ministerial Forum on Food Regulation.

[www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

Japan External Trade Organization [JETRO]. (2011). Specifications and Standards for Foods, Food Additives, etc. Under the Food Sanitation Act (Abstract) 2010.

[https://www.jetro.go.jp/ext\\_images/en/reports/regulations/pdf/foodext2010e.pdf](https://www.jetro.go.jp/ext_images/en/reports/regulations/pdf/foodext2010e.pdf) Ministry of Food and Drug Safety. (2020). Food Additives Code. [https://www.mfds.go.kr/eng/brd/m\\_15/view.do?seq=72432](https://www.mfds.go.kr/eng/brd/m_15/view.do?seq=72432)

Ministry of Health. (2008). Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0–2): A background paper (4<sup>th</sup> 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)

Ministry of Health and Welfare. (2022). Standards for Specification, Scope, Application and Limitation of Food Additives. <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0040084>

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=GRN\\_No&order=DESC&startrow=1&type=basic&search=669](https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=669&sort=GRN_No&order=DESC&startrow=1&type=basic&search=669)

## **Attachments**

- A. Draft variation to the Australia New Zealand Food Standards Code
- B. Draft Explanatory Statement

# Attachment A – 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**

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**

- (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>
<b>Substance</b>	<b>Permitted Form</b>	<b>Conditions of use</b>
1 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, <b>exclusive use period</b> 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 – Draft Explanatory Statement

### 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 amend the Code to permit the addition of bovine lactoferrin (bLf) as a nutritive substance to 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 prepared a draft a variation to the Code.

### 2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation ([www.legislation.gov.au](http://www.legislation.gov.au)).

If approved, this instrument would not be subject to the disallowance or sunseting 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 sunseting 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 sunseting 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 prepared 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 draft variation includes consequential amendments to the Code as a result of the above amendments.

#### **4. Documents incorporated by reference**

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

However, the 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 will include one round of public comment following an assessment and the preparation of a draft variation and associated assessment summaries.

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**

If approved, this instrument would be 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 draft variation would amend 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]** would substitute 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 draft variation would amend 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]** would amend 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]** would insert, 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 draft variation would amend Schedule 29.

**Item [4]** would amend 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]** would insert new section S29—5A into Schedule 29. The new section sets out the conditions of use of permitted nutritive substances in infant formula products.

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 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.

If the draft variation is approved, the effect of the draft variation would be that bLf would be permitted to be used as a nutritive substance in an IFP in accordance with the Code, subject to the following conditions:

- the amount of bLf in an IFP must not be greater than 40 mg per 100 kJ; and
- the following exclusive use permission applies:
  - bLf may only be sold under the brand 'Synlait' for use as a nutritive substance in an IFP during the exclusive use period i.e. the period commencing on the date of gazettal of the draft variation and ending 15 months after that date, and
  - once that period ends, the permission would revert to a general permission, i.e. bLf under any brand may then be sold for use as a nutritive substance in an IFP.