

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

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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 17 April 2023



Dr Nick Fletcher  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC 157 on 21 April 2023. 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>
<b>Substance</b>	<b>Permitted Form</b>	<b>Conditions of use</b>
Lactoferrin	Bovine lactoferrin	<ol style="list-style-type: none"> <li>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.</li> <li>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.</li> </ol>