

**Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other 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 19 March 2021



Glen Neal  
General Manager, Risk Management and Intelligence  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC 139 on 26 March 2021. 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 A1155 – 2'-FL and LNnT in infant formula and other 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

#### [1] Standard 2.9.1 is varied by

[1.1] omitting section 2.9.1—7, substituting

#### 2.9.1—7 **Restriction on addition to infant formula product of inulin-type fructans and galacto-oligosaccharides**

- (1) If an inulin-type fructan or a galacto-oligosaccharide is added to an infant formula product, the product must contain (taking into account both the naturally-occurring and added substances) no more than:
  - (a) if only \*inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or
  - (b) if only \*galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or
  - (c) if both inulin-type fructans and galacto-oligosaccharides are added:
    - (i) no more than 110 mg/100 kJ of inulin-type fructans; and
    - (ii) no more than 290 mg/100 kJ of combined inulin-type fructans and galacto-oligosaccharides.
- (2) An infant formula product to which an inulin-type fructan or a galacto-oligosaccharide is added must not contain any of the following added substances:
  - (a) 2'-O-fucosyllactose; or
  - (b) a combination of 2'-O-fucosyllactose and lacto-N-neotetraose.

[1.2] inserting after paragraph 2.9.1—24(1)(c)

- (ca) the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect; or
- (cb) the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect; or

#### [2] **Schedule 2** is varied by inserting in the table to section S2—2, in alphabetical order

EU/mg

Endotoxin units per milligram

#### [3] **Schedule 3** is varied by

[3.1] inserting in the table to subsection S3—2(2) in alphabetical order

2'-O-fucosyllactose

section S3—40

[3.2] inserting in the table to subsection S3—2(2) in alphabetical order

lacto-N-neotetraose

section S3—41

[3.3] inserting after subsection S3—39

#### **S3—40 Specification for 2'-O-fucosyllactose**

For 2'-O-fucosyllactose (2'-FL), the specifications are the following:

- (a) chemical name— $\alpha$ -L-fucopyranosyl-(1 $\rightarrow$ 2)- $\beta$ -D-galactopyranosyl-(1 $\rightarrow$ 4)-D-glucopyranose;
- (b) chemical formula— $C_{18}H_{32}O_{15}$ ;
- (c) CAS number—41263-94-9;
- (d) description—white to off white powder or agglomerates;
- (e) assay (water free) for sum of 2'-FL, lactose, difucosyllactose and fucose—not less than 96.0%;
- (f) assay (water free) 2'-FL—not less than 94.0%;
- (g) D-lactose—not more than 3.0%
- (h) L-fucose—not more than 1.0%
- (i) difucosyllactose—not more than 1.0%
- (j) 2'-fucosyl-D-lactulose—not more than 1.0%
- (k) pH (20°C, 5% solution)—3.2 to 5.0
- (l) water—not more than 5.0%
- (m) ash, sulphated—not more than 1.5%
- (n) acetic acid (as free acid and/or sodium acetate)—not more than 1.0%
- (o) residual proteins—not more than 0.01%
- (p) lead—not more than 0.1 mg/kg
- (q) microbiological:
  - (i) *salmonella*—absent in 25 g
  - (ii) total plate count—not more than 500 cfu/g
  - (iii) enterobacteriaceae—absent in 10 g
  - (iv) *cronobacter (Enterobacter) sakazakii*—absent in 10 g
  - (v) *listeria monocytogenes*—absent in 25 g
  - (vi) *bacillus cereus*—not more than 50 cfu/g
  - (vii) yeasts—not more than 10 cfu/g
  - (viii) moulds—not more than 10 cfu/g
  - (ix) residual endotoxins—not more than 10 EU/mg

## S3—41

### Specification for lacto-N-neotetraose

For lacto-N-neotetraose (LNnT), the specifications are the following:

- (a) chemical name— $\beta$ -D-galactopyranosyl-(1 $\rightarrow$ 4)-2-acetamido-2-deoxy- $\beta$ -D-glucopyranosyl-(1 $\rightarrow$ 3)- $\beta$ -D-galactopyranosyl-(1 $\rightarrow$ 4)-D-glucopyranose
- (b) chemical formula— $C_{26}H_{45}NO_{21}$
- (c) CAS number—13007-32-4
- (d) description—white to off white powder or agglomerates
- (e) assay (water free) for sum of LNnT, lactose, lacto-N-triose II, and *para*-lacto-N-hexaose—not less than 95.0%
- (f) assay (water free) LNnT—not less than 92.0%
- (g) D-lactose—not more than 3.0%
- (h) lacto-N-triose II—not more than 3.0%
- (i) *para*-lacto-N-neohexaose—not more than 3.0%
- (j) LNnT fructose isomer—not more than 1.0%
- (k) pH (20°C, 5% solution)—4.0 to 7.0
- (l) water—not more than 9.0%
- (m) ash, sulphated—not more than 1.5%
- (n) methanol—not more than 100 mg/kg
- (o) residual proteins—not more than 0.01%
- (p) lead—not more than 0.1 mg/kg
- (q) microbiological:

- (i) *salmonella*—absent in 25 g
- (ii) total plate count—not more than 500 cfu/g
- (iii) enterobacteriaceae—absent in 10 g
- (iv) *cronobacter (Enterobacter) sakazakii*—absent in 10 g
- (v) *listeria monocytogenes*—absent in 25 g
- (vi) *bacillus cereus*—not more than 50 cfu/g
- (vii) yeasts—not more than 10 cfu/g
- (viii) moulds—not more than 10 cfu/g
- (ix) residual endotoxins—not more than 10 EU/mg

**[4] Schedule 26** is varied by

[4.1] omitting subsections S26—3(1), (2), (2A), and (3), substituting

- (1) The table to subsection (4) and the table to subsection (7) list permitted food produced using gene technology.
- (2) Items 1(g), 2(m), 7(e), (g) and (h), and 9(a) of the table to subsection (4) are subject to the condition that their labelling must comply with section 1.5.2—4.

**Note** That section requires the statement ‘genetically modified’.

- (2A) Products containing beta-carotene from item 6(b) of the table to subsection (4) are subject to the condition that their labelling must comply with section 1.5.2—4.
- (3) Item 2(m) of the table to subsection (4) is also subject to the condition that, for the labelling provisions, unless the protein content has been removed as part of a refining process, the information relating to \*foods produced using gene technology includes a statement to the effect that the high lysine corn line LY038 has been genetically modified to contain increased levels of lysine.

[4.2] omitting the words ‘gene technology’ from the heading to the table to subsection (4), substituting the words ‘gene technology of plant origin’.

[4.3] inserting after the table to subsection (4)

- (5) A food listed in the table to subsection (7) must comply with any corresponding conditions listed in that table.
- (6) A source listed in the table to subsection (7) may contain additional copies of genes from the same strain.
- (7) The table for this subsection is:

**Food produced using gene technology of microbial origin**

| <b>Substance</b>             | <b>Source</b>   | <b>Conditions of use</b>  |
|------------------------------|---|---|
| <b>1 2'-O-fucosyllactose</b> | (a) <i>Escherichia coli</i> K-12 containing the gene for alpha-1,2-fucosyltransferase from <i>Helicobacter pylori</i> | <ul style="list-style-type: none"> <li>1. May only be added to infant formula products.</li> <li>2. During the exclusive use period, may only be sold under the brand GlyCare.</li> <li>3. For the purposes of condition 2 above, <b>exclusive use period</b> means the period commencing on the date of gazettal of the <i>Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation</i> and ending 15 months after that date.</li> </ul> |

| <b>Substance</b>             | <b>Source</b>  | <b>Conditions of use</b>  |
|------------------------------|--|---|
| <b>2 Lacto-N-neotetraose</b> | (a) <i>Escherichia coli</i> K-12 containing the gene for beta-1,3-N-acetylglucosaminyltransferase from <i>Neisseria meningitidis</i> and the gene for beta-1,4-galactosyltransferase from <i>Helicobacter pylori</i> | <ol style="list-style-type: none"> <li>1. May only be added to infant formula products in combination with 2'-O-fucosyllactose.</li> <li>2. During the exclusive use period, may only be sold under the brand GlyCare.</li> <li>3. For the purposes of condition 2 above, <b>exclusive use period</b> means the period commencing on the date of gazettal of the <i>Food Standards (Application A1155 – 2'-FL and LNnT in infant formula and other products) Variation</i> and ending 15 months after that date.</li> </ol> |

[5] **Schedule 29** is varied by

[5.1] omitting section S29—5, substituting

**S29—5 Infant formula products—substances permitted as nutritive substances**

For section 2.9.1—5, the table is set out below.

**Infant formula products—substances permitted for use as nutritive substances**

| <b>Column 1</b>  | <b>Column 2</b>  | <b>Column 3</b>                  | <b>Column 4</b>   |
|--|--|----------------------------------|---|
| <i>Substance</i>   | <i>Permitted forms</i>   | <i>Minimum amount per 100 kJ</i> | <i>Maximum amount per 100 kJ</i>                                |
| 2'-O-fucosyllactose permitted for use by Standard 1.5.2  | 2'-O-fucosyllactose  |                                  | 96 mg   |
| A combination of: 2'-O-fucosyllactose permitted for use by Standard 1.5.2; and lacto-N-neotetraose permitted for use by Standard 1.5.2 | 2'-O-fucosyllactose and lacto-N-neotetraose                          |                                  | 96 mg which contains not more than 24 mg of lacto-N-neotetraose |
| Adenosine-5'-monophosphate   | Adenosine-5'- monophosphate  | 0.14 mg                          | 0.38 mg   |
| L-carnitine  | L-carnitine  | 0.21 mg                          | 0.8 mg  |
| Choline  | Choline chloride<br>Choline bitartrate                               | 1.7 mg                           | 7.1 mg  |
| Cytidine-5'-monophosphate  | Cytidine-5'-monophosphate  | 0.22 mg                          | 0.6 mg  |
| Guanosine-5'-monophosphate   | Guanosine-5'-monophosphate<br>Guanosine-5'-monophosphate sodium salt | 0.04 mg                          | 0.12 mg   |
| Inosine-5'-monophosphate   | Inosine-5'-monophosphate<br>Inosine-5'-monophosphate sodium salt     | 0.08 mg                          | 0.24 mg   |
| Lutein   | Lutein from <i>Tagetes erecta</i> L.                                 | 1.5 µg                           | 5 µg  |
| Inositol   | Inositol   | 1.0 mg                           | 9.5 mg  |
| Taurine  | Taurine  | 0.8 mg                           | 3 mg  |
| Uridine-5'-monophosphate   | Uridine-5'-monophosphate sodium salt                                 | 0.13 mg                          | 0.42 mg   |