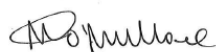


Food Standards (Application A1190 – 2'-FL in infant formula and other products) Variation

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 12 January 2022



Dr Matthew O'Mullane
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 146 on 20 January 2022. 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 A1190 – 2'-FL 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.

4 Order in which amendments in the Schedule take effect

Amendments in the Schedule take effect in numerical order.

Schedule

[1] Standard 2.9.1 is varied by omitting “2'-O-fucosyllactose” (wherever occurring) in subsection 2.9.1—7(2), substituting “2'-fucosyllactose”

[2] Schedule 3 is varied by

[2.1] omitting in the table to subsection S3—2(2)

2'-O-fucosyllactose

section S3—40

and substituting, in alphabetical order

2'-fucosyllactose sourced from *Escherichia coli* K-12

section S3—40

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

2'-fucosyllactose sourced from *Escherichia coli* BL21

section S3—45

[2.3] omitting the heading for section S3—40, substituting

S3—40 Specification for 2'-fucosyllactose sourced from *Escherichia coli* K-12

[2.4] omitting “2'-O-fucosyllactose (2'-FL)” in section S3—40, substituting “2'-fucosyllactose (2'-FL) sourced from *Escherichia coli* K-12”

[2.5] inserting after subsection S3—44

S3—45 Specification for 2'-fucosyllactose sourced from *Escherichia coli* BL21

For 2'-fucosyllactose (2'-FL) sourced from *Escherichia coli* BL21, the specifications are the following:

- (a) chemical name— α -L-fucopyranosyl-(1→2)- β -D-galactopyranosyl-(1→4)-D-glucopyranose
- (b) chemical formula— $C_{18}H_{32}O_{15}$
- (c) CAS number—41263-94-9
- (d) description—either a white to ivory powder, or a colourless to slightly yellow liquid
- (e) 2'-FL—not less than 90.0%
- (f) D-lactose—not more than 5.0%
- (g) L-fucose—not more than 3.0%
- (h) 3-fucosyllactose—not more than 5.0%

- (i) difucosyllactose—not more than 5.0%
- (j) fucosyl-galactose—not more than 3.0%
- (k) glucose—not more than 3.0%
- (l) galactose—not more than 3.0%
- (m) water—not more than 9.0% for powder, not applicable for liquid
- (n) solids—45% w/v ($\pm 5\%$) dry matter in water, not applicable for powder
- (o) ash, sulphated—not more than 0.5%
- (p) residual proteins—not more than 0.01%
- (q) lead—not more than 0.02 mg/kg
- (r) arsenic—not more than 0.2 mg/kg
- (s) cadmium—not more than 0.1 mg/kg
- (t) mercury—not more than 0.5 mg/kg
- (u) microbiological:
 - (i) *Salmonella*—absent in 100 g for powder, absent in 200 mL for liquid
 - (ii) total plate count—not more than 10000 cfu/g for powder, not more than 5000 cfu/g for liquid
 - (iii) coliform/Enterobacteriaceae—absent in 11 g for powder, absent in 22 mL for liquid
 - (iv) *Cronobacter sakazakii*—absent in 100 g for powder, absent in 200 mL for liquid
 - (v) yeast and mould—not more than 100 cfu/g for powder, not more than 50 cfu/g for liquid
 - (vi) aflatoxin M1—not more than 0.025 $\mu\text{g/kg}$
 - (vii) endotoxins—not more than 10 EU/mg
 - (viii) GMO detection—not detected.

[3] Schedule 26 is varied by

[3.1] omitting item 1 in the table to subsection S26—3(7), substituting

1 2'-fucosyllactose	(a) <i>Escherichia coli</i> K-12 containing the gene for alpha-1,2-fucosyltransferase from <i>Helicobacter pylori</i>	<ol style="list-style-type: none"> 1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare. 3. For the purposes of condition 2 above, exclusive use period 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.
----------------------------	---	---

(b) *Escherichia coli* BL21
containing the gene for
alpha-1,2-
fucosyltransferase from
Escherichia coli O126

1. May only be added to infant formula products.
2. During the exclusive use period, may only be sold under the brand CHR. HANSEN™ 2'-FL.
3. For the purposes of condition 2 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1190 – 2'-FL in infant formula and other products) Variation* and ending 15 months after that date.

[3.2] omitting "2'-O-fucosyllactose" in item 2 in the table to subsection S26—3(7), substituting "2'-fucosyllactose"

[4] **Schedule 29** is varied by omitting "2'-O-fucosyllactose" (wherever occurring) in the table to section 2.9.1—5, substituting "2'-fucosyllactose"