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Food Standards

Amendment No. 247

The following instruments are separate instruments in the Federal Register of Legislation and are known collectively in the Food Standards Gazette as Amendment No. 247

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Food Standards (Application A1324 – 3-fucosyllactose as a nutritive substance 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 9 January 2026



Christel Leemhuis
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 187 on 20 January 2026. 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 A1324 – 3-fucosyllactose as a nutritive substance 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

Schedule 3—Identity and purity

[1] Subsection S3—2(2) (table, after the table item dealing with 2'-fucosyllactose and difucosyllactose sourced from *Escherichia coli* K-12)

Insert:

3-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori* section S3—56

[2] After section S3—55

Insert:

S3—56 Specification for 3-fucosyllactose sourced from *Escherichia coli* K-12

For 3-fucosyllactose (3-FL) sourced from *Escherichia coli* K-12 containing the gene for alpha-1,3-fucosyl-transferase from *Helicobacter pylori*, the specifications are the following:

- (a) chemical name— β -D-Galactopyranosyl-(1-4)-[α -L-fucopyranosyl-(1-3)]-D-glucose;
- (b) chemical formula— $C_{18}H_{32}O_{15}$;
- (c) molecular weight—488.44 g/mol;
- (d) CAS number—41312-47-4;
- (e) description—white to off-white powder or agglomerates;
- (f) sum of saccharides (3-FL, D-lactose, L-fucose, 3-fucosyl-lactulose)—not less than 92.0% (water free);
- (g) 3-FL—not less than 90.0% (water free);
- (h) L-fucose—not more than 1.0%;
- (i) D-lactose—not more than 5.0%;
- (j) 3-fucosyllactulose—not more than 1.5%;
- (k) Sum of other carbohydrates—not more than 5.0%;
- (l) pH (20°C, 5% solution)—3.2 to 7.0;
- (m) water—not more than 6.0%;
- (n) ash, sulphated—not more than 0.5%;
- (o) residual proteins—not more than 0.01%;
- (p) lead—not more than 0.05 mg/kg;
- (q) microbiological:
 - (i) aerobic mesophilic bacteria total count—not more than 1,000 cfu/g;
 - (ii) *Enterobacteriaceae*—absent in 10 g;
 - (iii) yeasts—not more than 100 cfu/g;
 - (iv) moulds—not more than 100 cfu/g;
 - (v) residual endotoxins—not more than 10 EU/mg.

Schedule 26—Genetically modified food

[3] Subsection S26—3(7) (table)

Insert:

8	3-fucosyllactose	<i>Escherichia coli</i> K-12 containing the gene for alpha-1,3-fucosyl-transferase 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 A1324 – 3-fucosyllactose as a nutritive substance in infant formula products) Variation</i> and ending 15 months after that date.
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Schedule 29—Special purpose foods

[4] Section S29—7 (table, after the table item dealing with 2'-fucosyllactose permitted for use by Standard 1.5.2)

Insert:

3-fucosyllactose permitted for use by Standard 1.5.2	80 mg
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[5] Section S29—8 (table, after the table item dealing with 2'-fucosyllactose permitted for use by Standard 1.5.2)

Insert:

3-fucosyllactose permitted for use by Standard 1.5.2	80 mg
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[6] Section S29—9 (table, after the table item dealing with 2'-fucosyllactose permitted for use by Standard 1.5.2)

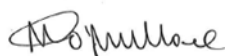
Insert:

3-fucosyllactose permitted for use by Standard 1.5.2	3-fucosyllactose
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Food Standards (Application A1333 – Food derived from purple tomato lines containing event Del/Ros1-N) 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 the variation.

Dated 09 January 2026



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 187 on 20 January 2026. 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 A1333 – Food derived from purple tomato lines containing event Del/Ros1-N) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 26—Genetically modified food

[1] Subsection S26—3(2) (not including the note)

Repeal the subsection, substitute:

(2) Items 1(g), 1(i), 2(m), 7(e), 7(g), 7(h), 9(a) and 12(a) of the table to subsection (4) are subject to the condition that their labelling must comply with section 1.5.2—4.

[2] Subsection S26—3(4) (after table item 11)

Add:

12	Tomato	(a) purple tomato lines containing event Del/Ros1-N (see subsection (2))
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