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Food Standards

Amendment No. 223

The following instruments are separate instruments in the Federal Register of Legislation and are known collectively in the Food Standards Gazette as Amendment No. 223

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Food Standards (Application A1264 – Food derived from drought-tolerant and herbicide-tolerant soybean line IND-00410-5) 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 the variation.

22 November 2023

Christel Leemhuis, General Manager Science and Risk Assessment
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 163 on 30 November 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 A1264 – Food derived from drought-tolerant and herbicide-tolerant soybean line IND-00410-5) 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—Food produced using gene technology

[1] Subsection S26—3(4) (table item 7, column headed "*Food derived from:*")

Insert:

(r) drought-tolerant and herbicide-tolerant soybean line IND-00410-5

Food Standards (Application A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances 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.

23 November 2023

Owen Walsh, Section Manager – Standards Management
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 163 on 30 November 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 A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances 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] Subsection 2.9.1—7(2)

Repeal the subsection.

Schedule 3—Identity and purity

[2] Subsection S3—2(2) (table)

Insert:

2′-fucosyllactose and difucosyllactose sourced from *Escherichia coli K-12*	section S3—47
lacto-N-tetraose sourced from *Escherichia coli* K-12	section S3—48
6′-sialyllactose sodium salt sourced from *Escherichia coli* K-12	section S3—49
3′-sialyllactose sodium salt sourced from *Escherichia coli* K-12	section S3—50

[3] After section S3—46

Insert:

S3—47 Specification for a combination of 2′-fucosyllactose and difucosyllactose sourced from *Escherichia coli K-12*

For a mixture of 2′-fucosyllactose (2′-FL) and difucosyllactose (DFL) sourced from *Escherichia coli K-12* containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*, the specifications are the following:

(a) chemical names:
  (i) for 2′-FL—α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;
  (ii) for DFL—α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-[α-L-fucopyranosyl-(1→3)]-D-glucose;

(b) chemical formulas:
  (i) for 2′-FL—$C_{18}H_{32}O_{15}$;
  (ii) for DFL—$C_{24}H_{42}O_{19}$;

(c) molecular weights:
  (i) for 2′-FL—488.44 g/mol;
  (ii) for DFL—634.58 g/mol;

(d) CAS numbers:
  (i) for 2′-FL—41263-94-9;
  (ii) for DFL—20768-11-0;

(e) description—white, white to off-white, or off-white powder, agglomerates, or powder with agglomerates;

(f) 2′-FL—not less than 75.0% (water free);

(g) DFL—not less than 5.0% (water free);

(h) sum of 2′-FL and DFL—not less than 85.0% (water free);

(i) sum of human identical milk saccharides: 2′-FL, DFL, D-lactose, L-fucose, 3-fucosyllactose —not less than 92.0% (water free);

(j) D-lactose—not more than 10%;

(k) L-fucose—not more than 1.0%;

(l) 2'-fucosyl-D-lactulose—not more than 2.0%;

(m) pH (20°C, 5% solution)—4.0-6.0;

(n) water—not more than 6.0%;

(o) ash, sulphated—not more than 0.8%;

(p) residual protein—not more than 0.01%;

(q) lead—not more than 0.1 mg/kg;

(r) 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.

S3—48 Specification for lacto-N-tetraose sourced from *Escherichia coli K-12*

For lacto-N-tetraose (LNT) sourced from *Escherichia coli K-12* containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitides* and the gene for beta-1.3-galactosyltransferase from *Helicobacter pylori*, the specifications are the following:

(a) chemical name—β-D-galactopyranosyl-(1→3)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucose;

(b) chemical formula—$C_{26}H_{45}NO_{21}$;

(c) molecular weight—707.63 g/mol;

(d) CAS number—14116-68-8;

(e) description—white, white to off-white, or off-white powder, agglomerates, or powder with agglomerates;

(f) LNT—not less than 70.0% (water free);

(g) sum of human identical milk saccharides: LNT, D-lactose, lacto-N-triose II—not less than 90.0% (water free);

(h) D-lactose—not more than 12.0%;

(i) lacto-N-triose II—not more than 10.0%;

(j) *para*-lacto-N-hexaose-2—not more than 3.5%;

(k) β-D-Galactopyranosyl-(1→3)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-fructose (LNT fructose isomer)—not more than 1.0%;

(l) pH (20°C, 5% solution)—4.0-6.0;

(m) water—not more than 6.0%;

(n) residual protein—not more than 0.01%;

(o) ash, sulphated—not more than 0.5%;

(p) lead—not more than 0.1 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.

S3—49 Specification for 6′-sialyllactose sodium salt sourced from *Escherichia coli K-12*

For 6′-sialyllactose (6′-SL) sodium salt sourced from *Escherichia coli K-12* containing the gene for alpha-2,6-sialyltransferase from *Photobacterium damsela* and CMP-Neu5Ac synthetase, Neu5Ac synthetase, *N*-acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*, the specifications are the following:

(a) chemical name—N-acetyl-α-D-neuraminyl-(2→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt;

(b) chemical formula—$C_{23}H_{38}NO_{19}Na$;

(c) molecular weight—655.53 g/mol;

(d) CAS number—157574-76-0;

(e) description—white, white to off-white, or off-white powder, agglomerates, or powder with agglomerates;

(f) 6′-SL sodium salt—not less than 90.0% (water free);

(g) sum of human identical milk saccharides: 6′-SL sodium salt, D-lactose, sialic acid—not less than 94.0% (water free);

(h) D-lactose—not more than 5.0%;

(i) sialic acid—not more than 2.0%;

(j) sialyl-lactulose—6’- isomer—not more than 3.0%;

(k) sodium—2.5-4.5%;

(l) chloride—not more than 1.0%;

(m) pH (20°C, 5% solution)—4.5-6.0;

(n) water—not more than 6.0%;

(o) residual protein—not more than 0.01%;

(p) lead—not more than 0.1 mg/kg;

(q) microbiological:

(i) aerobic mesophilic total plate 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.

S3—50 Specification for 3′-sialyllactose sodium salt sourced from *Escherichia coli K-12*

For 3′-sialyllactose (3′-SL) sodium salt sourced from *Escherichia coli K-12* containing the gene for alpha-2,3-sialyltransferase from *Neisseria meningitides* and CMP-Neu5Ac synthetase, Neu5ac synthase, *N*-acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*, the specifications are the following:

(a) chemical name—N-acetyl-α-D-neuraminyl-(2→3)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt;

(b) chemical formula—$C_{23}H_{38}NO_{19}Na$;

(c) molecular weight—655.53 g/mol;

(d) CAS number—128596-80-5;

(e) description—white, white to off-white, or off-white powder, agglomerates, or powder with agglomerates;

(f) 3′-SL sodium salt—not less than 88.0% (water free);

(g) sum of human identical milk saccharides: 3′-SL sodium salt, D-lactose, sialic acid—not less than 90.0% (water free);

(h) D-lactose—not more than 5.0%;

(i) sialic acid—not more than 1.5%;

(j) sialyl-lactulose-3′-isomer—not more than 5.0%;

(k) sodium—2.5-4.5%;

(l) chloride—not more than 1.0%;

(m) pH (20°C, 5% solution)—4.5-6.0;

(n) water—not more than 8.0%;

(o) residual protein—not more than 0.01%;

(p) lead—not more than 0.1 mg/kg;

(q) microbiological:

(i) aerobic mesophilic total plate 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—Food produced using gene technology

[4] Subsection S26—3(7) (table)

Insert:

4	**A combination of 2′-fucosyllactose and difucosyllactose**	*Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare 2′-FL/DFL 8001. 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 A1265 – 2′-FL/DFL, LNT, 6′-SL sodium salt and 3′-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.
5	**lacto-N-tetraose**	*Escherichia coli* K-12 containing the gene for beta-1,3- N-acetylglucosaminyltransferase from *Neisseria meningitides* and the gene for beta-1,3- galactosyltransferase from *Helicobacter pylori*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare LNT8001. 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 A1265 – 2′-FL/DFL, LNT, 6′-*

			SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation and ending 15 months after that date.
6	**6′-sialyllactose sodium salt**	*Escherichia coli* K-12 containing the gene for alpha-2,6-sialyltransferase from *Photobacterium damsela* and CMP-Neu5Ac synthetase, Neu5Ac synthase, N-acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare 6SL 9001. 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 A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.
7	**3′-sialyllactose sodium salt**	*Escherichia coli* K-12 containing the gene for alpha-2,3-sialyltransferase from *Neisseria meningitides* and CMP-Neu5Ac synthetase, Neu5Ac synthase, N-acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand GlyCare 3SL 9001. 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 A1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products) Variation* and ending 15 months after that date.

Schedule 29—Special purpose foods

[5] Section S29—5 (table)

Insert each of the following substances in alphabetical order:

3'-sialyllactose sodium salt permitted for use by Standard 1.5.2	3'-sialyllactose sodium salt	8 mg
6'-sialyllactose sodium salt permitted for use by Standard 1.5.2	6'-sialyllactose sodium salt	16 mg
A combination of 2′-fucosyllactose and difucosyllactose, permitted for use by Standard 1.5.2	2'-fucosyllactose and difucosyllactose	96 mg

lacto-N-tetraose permitted for use by Standard 1.5.2	lacto-N-tetraose	32 mg

Food Standards (Application A1266 – Endo-1,4-beta-xylanase from GM *Trichoderma reesei* (gene donor: *Fusarium verticillioides*) as a processing aid) 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.

23 November 2023

Owen Walsh, Section Manager – Standards Management

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 163 on 30 November 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 A1266 – Endo-1,4-beta-xylanase from GM* Trichoderma reesei *(gene donor:* Fusarium verticillioides*) as a processing aid) 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 18—Processing aids

[1] Subsection S18—9(3) (table)

Insert:

Endo-1,4-β-xylanase, protein engineered variant, (EC 3.2.1.8) sourced from *Trichoderma reesei*, containing the endo-1,4-ß-xylanase gene from *Fusarium verticillioides*	For use in starch processing and the production of potable alcohol	GMP