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Amendment No. 198

The following instruments are separate instruments in the Federal Register of Legislation and are known collectively in the Food Standards Gazette as Amendment No.198.

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Food Standards (Application A1155 – 2′-FL and LNnT 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 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——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— 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——β-D-galactopyranosyl-(1→4)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→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

Substance	***Source***	***Conditions of use***
1 2′-O-fucosyllactose	(a) *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. 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 A1155 – 2'-FL and LNnT in infant formula and other products) Variation* and ending 15 months after that date.

Substance	*Source*	*Conditions of use*
2 Lacto-N-neotetraose	(a) *Escherichia coli* K-12 containing the gene for beta-1,3-N-acetylglucosaminyltransfera se from *Neisseria meningitides* and the gene for beta-1,4-galactosyltransferase from *Helicobacter pylori*	1. May only be added to infant formula products in combination with 2′-O-fucosyllactose. 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 *Food Standards (Application A1155 – 2′-FL and LNnT in infant formula and other products) Variation* and ending 15 months after that date.

[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

Column 1	*Column 2*	*Column 3*	*Column 4*
Substance	*Permitted forms*	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*
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	1.7 mg	7.1 mg
	Choline bitartrate		
Cytidine-5′-monophosphate	Cytidine-5′-monophosphate	0.22 mg	0.6 mg
Guanosine-5′-monophosphate	Guanosine-5′-monophosphate	0.04 mg	0.12 mg
	Guanosine-5′-monophosphate sodium salt		
Inosine-5′-monophosphate	Inosine-5′-monophosphate	0.08 mg	0.24 mg
	Inosine-5′-monophosphate sodium salt		
Lutein	Lutein from *Tagetes erecta 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

Food Standards (Application A1175 – Rapeseed protein isolate as a novel food) 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 19 March 2021

Joanna Richards
Standards Management Officer
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. For the purposes of clause 3 of the variation commencement is 30 June 2021.

1 Name

This instrument is the *Food Standards (Application A1175 – Rapeseed protein isolate as a novel food) 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 30 June 2021.

Schedule

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

[1.1] inserting the following row into the table to S3—2(2), in alphabetical order –

rapeseed protein isolate	section S3—40

[1.2] inserting after section S3—39

S3—40 Specification for rapeseed protein isolate

For rapeseed protein isolate, the specifications are the following:

(a) Composition:
- (i) Total protein (%) – no less than 90; and
- (ii) Carbohydrates (%) – no more than 7; and
- (iii) Fat (%) – no more than 5; and
- (iv) Ash (%) – no more than 5; and
- (v) Moisture (%) – no more than 7;

(b) Purity:
- (i) Glucosinolates (µmol/g) – no more than 1;
- (ii) Erucic acid (%) – no more than 0.005;
- (iii) Phytates (% w/w) – no more than 1.5;

(c) Metals:
- (i) Lead (mg/kg) – no more than 0.5;

(d) Microbiological:
- (i) Total plate count (cfu/g) no more than 10,000; and
- (ii) *E. coli* (cfu/10g) absent; and
- (iii) *Salmonella* spp. (cfu/25g) absent; and
- (iv) Yeasts and moulds (cfu/g) less than 100.

[2] **Schedule 25** is varied by inserting into the table to section S25—2, in alphabetical order

Rapeseed protein isolate	1. Must be derived from rapeseed press cake retained after oil pressing from the seeds of one or more of: (a) *Brassica napus*; (b) *Brassica rapa*; or (c) *Brassica juncea*. 2. Must not be added to: (a) infant formula products; and (b) food for infants. 3. Must comply with the specifications for rapeseed protein isolate listed in section S3—40.

Food Standards (Application A1180 – Natural Glycolipids as a preservative in non-alcoholic beverages) 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 19 March 2021

Joanna Richards
Standards Management Officer
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 29 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 A1180 – Natural Glycolipids as a preservative in non-alcoholic beverages) 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] **Schedule 2** is varied by inserting in the table to section S2—2 in alphabetical order

MPN	most probable number

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

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

Sweet osmanthus ear glycolipids	section S3—43

[2.2] inserting after section S3—42

S3—43 Specification for sweet osmanthus ear glycolipids

For sweet osmanthus ear glycolipids, the specifications are the following:

(a) CAS number—2205009-17-0;

(b) chemical structure—a mixture of long-chain glycolipids obtained from the fermentation and filtration of the non-GMO *Dacryopinax spathularia* strain MUCL 53181;

(c) description—off-white to ivory powder;

(d) pH—between 5.0 and 7.0 (1% aqueous solution);

(e) water—less than 5%;

(f) protein—less than 3%;

(g) fat—less than 2%;

(h) total glycolipid content on a dry weight basis for the powder—no less than 93%;

(i) lead—not more than 2 mg/kg;

(j) arsenic—not more than 1 mg/kg;

(k) cadmium— not more than 1 mg/kg;

(l) mercury— not more than 1 mg/kg;

(m) microbial limits:

  (i) total aerobic microbial count—not more than 100 cfu/g;

  (ii) total yeast and mould count—not more than 10 cfu/g;

  (iii) coliforms—not more than 3 MPN/g;

  (iv) *Escherichia coli*—not more than 3 MPN/g.

[3] **Schedule 8** is varied by

[3.1] inserting in the table to section S8—2 entitled ‘Food additive names—alphabetical listing’, in alphabetical order

Sweet osmanthus ear glycolipids	–

[3.2] inserting in the table to section S8—2 entitled ‘Food additive names—numerical listing’, after the entry for **‘**Sodium hydrosulphite**’**

–	Sweet osmanthus ear glycolipids

[4] **Schedule 15** is varied by

[4.1] inserting in item 14.1.2 of the table to section S15–5, after the heading 'Fruit and vegetable juices and fruit and vegetable juice products'

Sweet osmanthus ear glycolipids	100	

[4.2] inserting in item 14.1.3 of the table to section S15–5, after the entry for 'Quinine'

Sweet osmanthus ear glycolipids	50	

[4.3] inserting in item 14.1.4 of the table to section S15–5, after the entry for 'Monk fruit extract (luo han guo extract)'

Sweet osmanthus ear glycolipids	20	

[4.4] inserting in item 14.1.5 of the table to section S15–5, after the entry for 'Additives permitted at GMP'

Sweet osmanthus ear glycolipids	10	

[4.5] inserting in item 14.2.1 of the table to section S15–5, after the heading 'Beer and related products'

Sweet osmanthus ear glycolipids	100	Only beer where the alcohol has been removed

Food Standards (Application A1186 – Soy Leghemoglobin in meat analogue 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 the variation.

Dated 19 March 2021

Joanna Richards
Standards Management Officer
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 1 Name

This instrument is the *Food Standards (Application A1186 – Soy Leghemoglobin in meat analogue 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 1.3.2 is varied by inserting after section 1.3.2—7

1.3.2—8 Use of soy leghemoglobin as a nutritive substance

(1) Iron in the form of soy leghemoglobin must not be used as a nutritive substance in a food other than a meat analogue product to which section S17—4 applies.

(2) For the purposes of subsection (1), soy leghemoglobin must not be present in a meat analogue product in its raw state at a concentration greater than 0.8%.

[2] Schedule 3 is varied by

[2.1] omitting from Note 1 the words 'Section 1.1.1—15 requires', substituting 'Sections 1.1.1—15 and S26—3 require'

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

soy leghemoglobin preparation	section S3—42

[2.3] inserting after section S3—41

S3—42 Specification for a soy leghemoglobin preparation

Note Subsections S26—3(5) and (7) require a soy leghemoglobin preparation to comply with the specifications set out in this section.

For a soy leghemoglobin preparation, the specifications are the following:

(a) soy leghemoglobin protein—maximum 9.0%;
(b) soy leghemoglobin protein purity—minimum 65%;
(c) appearance—dark red concentrated liquid;
(d) solids— maximum 26%;
(e) fat—maximum 2.0%;
(f) carbohydrate—maximum 6.0%;
(g) pH—5-10;
(h) moisture—maximum 90%;
(i) ash—maximum 4.0%;
(j) lead—maximum 0.4 mg/kg;
(k) arsenic—maximum 0.05 mg/kg;
(l) mercury—maximum 0.05 mg/kg;
(m) cadmium—maximum 0.2 mg/kg;
(n) microbiological:
    (i) *Escherichia coli*—negative to test;
    (ii) *Salmonella spp*.—negative to test;
    (iii) Listeria monocytogenes—negative to test.

[3] Schedule 17 is varied by

[3.1] inserting in Column 2 of the table to section S17—3 for the mineral 'Iron', in alphabetical order

	Soy leghemoglobin in a soy leghemoglobin preparation that is listed in Schedule 26 and complies with any corresponding conditions listed in that Schedule.

[3.2] omitting from the table to section S17—4, under the heading 'Analogues derived from legumes'

Analogues of meat, where no less than 12% of the energy value of the food is derived from protein, and the food contains 5 g protein per serve of the food

substituting

Analogues of meat, where no less than 12% of the energy value of the food is derived from protein, and the food contains no less than 5 g protein per serve of the food

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

[4.1] inserting in subsection S26—2(2), in alphabetical order

soy leghemoglobin preparation means a cell lysate preparation that:

(a) is derived from *Pichia pastoris* containing the gene for leghemoglobin c2 from *Glycine max*; and

(b) contains soy leghemoglobin.

[4.2] inserting in the table to subsection S26—3(7), in numerical order

3	**Soy leghemoglobin preparation**	*Pichia Pastoris* containing the gene for leghemoglobin c2 from *Glycine max*	1. May only be added to a meat analogue product to enable the use in that product of soy leghemoglobin as a nutritive substance in accordance with Standard 1.3.2. 2. Must comply with the specifications set out in section S3—42.