



Amendment No. 240

The following instruments are separate instruments in the Federal Register of Legislation and are known collectively in the Food Standards Gazette as Amendment No. 240

Table of contents

- **Food Standards (Application A1279 – *Lentinula edodes* (Shiitake mushroom) mycelia as a processing aid) Variation**
- **Food Standards (Application A1307 – Milk fat globule membrane as a nutritive substance in infant formula products) Variation**
- **Food Standards (Application A1308 – 2'-FL from GM *Escherichia coli* W in infant formula products) Variation**
- **Food Standards (Application A1310 – Food derived from insect-protected soybean line MON94637) Variation**
- **Food Standards (Application A1311 – Prolyl oligopeptidase from GM *Trichoderma reesei* as a processing aid) Variation**
- **Food Standards (Proposal P1064 – Australian only Infant Formula Product Standard) Variation**

ISSN 1446-9685

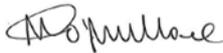
© Commonwealth of Australia 2025

This work is copyright. You may download, display, print and reproduce this material in unaltered form only (retaining this notice) for your personal, non-commercial use or use within your organisation. All other rights are reserved. Requests and inquiries concerning reproduction and rights should be addressed to The Information Officer, Food Standards Australia New Zealand, PO Box 5423, KINGSTON ACT 2604 or by email information@foodstandards.gov.au.

Food Standards (Application A1279 – *Lentinula edodes* (Shiitake mushroom) mycelia as a processing aid) 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 10 July 2025



Matthew O'Mullane, General Manager, Food Safety
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 180 on 22 July 2025. 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 A1279 – Lentinula edodes (Shiitake mushroom) mycelia 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

Standard 1.3.3—Processing aids

[1] After section 1.3.3—13

Insert:

1.3.3—14 Fermentation aid—a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia

- (1) In this section, a **fermented preparation** means a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia.
- (2) A fermented preparation may be *used as a processing aid to perform the technological purpose of a fermentation aid in fermentation of any of the following foods if the conditions listed in subsections (3) and (4) are complied with:
 - (a) pea protein;
 - (b) rice protein;
 - (c) pea and rice protein.
- (3) The proportion of the fermented preparation that is used is no more than the maximum level necessary to achieve the technological purpose listed in subsection (2) under conditions of GMP.
- (4) The fermented preparation must be produced from a glycerol stock of *Lentinula edodes* (shiitake mushroom) mycelia that complies with each of the following specifications:
 - (a) species—*Lentinula edodes*;
 - (b) arsenic—not more than 10 µg/kg;
 - (c) cadmium—not more than 5 µg/kg;
 - (d) lead—not more than 5 µg/kg;
 - (e) mercury—not more than 5 µg/kg;
 - (f) aerobic plate count—not more than 10 cfu/g.

Food Standards (Application A1307 – Milk fat globule membrane 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 10 July 2025



Christel Leemhuis, General Manager, Public Health
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 180 on 22 July 2025. 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 A1307 – Milk fat globule membrane 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)

Insert:

Bovine milk fat globule membrane-enriched whey protein concentrate section S3—53

[2] After section S3—52

Insert:

S3—53 Specification for bovine milk fat globule membrane-enriched whey protein concentrate

- (1) In this section, bovine milk fat globule membrane-enriched whey protein concentrate is a preparation of cow's milk consisting of lipids and proteins.
- (2) For bovine milk fat globule membrane-enriched whey protein concentrate, the specifications are the following:
 - (a) description—off white powder;
 - (b) total protein—not less than 69.0% and not more than 76.0%;
 - (c) lactose—not more than 2.0%;
 - (d) fat—not less than 16.0% and not more than 22.0%;
 - (e) phospholipids—not less than 6.0% and not more than 10.0%;
 - (f) sphingomyelin—not less than 1.3% and not more than 2.3%;
 - (g) ash—not more than 3.0%;
 - (h) moisture—not more than 5.0%;
 - (i) arsenic—not more than 0.2 mg/kg;
 - (j) cadmium—not more than 0.1 mg/kg;
 - (k) lead—not more than 0.05 mg/kg;
 - (l) mercury—not more than 0.02 mg/kg;
 - (m) microbial limits:
 - (i) total plate count (30°C)—not more than 10000 cfu/g;
 - (ii) total plate count (55°C)—not more than 1000 cfu/g;
 - (iii) *Bacillus cereus*—not more than 50 cfu/g;
 - (iv) Sulphite-reducing *Clostridia*—not more than 10 cfu/g;
 - (v) *Enterobacteriaceae*—not more than 10 cfu/g;
 - (vi) Coagulase-positive *staphylococci*—absent in 1 g;
 - (vii) Yeast and moulds—not more than 10 cfu/g.

Schedule 29—Special purpose foods

[3] Section S29—7 (table)

Insert:

Milk fat globule membrane-enriched whey protein concentrate	0.14 g	0.28 g
-------------------------------------------------------------	--------	--------

[4] Section S29—8 (table)

Insert:

Milk fat globule membrane-enriched whey protein concentrate	0.14 g	0.28 g
-------------------------------------------------------------	--------	--------

[5] Section S29—9 (table)

Insert:

Milk fat globule membrane-enriched whey protein concentrate	Bovine milk fat globule membrane-enriched whey protein concentrate
-------------------------------------------------------------	--------------------------------------------------------------------

[6] Section S29—9A (table)

Insert:

Milk fat globule membrane-enriched whey protein concentrate	Bovine milk fat globule membrane-enriched whey protein concentrate	<ol style="list-style-type: none">1. During the exclusive use period, may only be sold under the brand Lactrodan® MFGM-10 for *use as a nutritive substance in an infant formula product.2. For the purposes of condition 1 above, exclusive use period means the period commencing on the date of gazettal of the <i>Food Standards (Application A1307 – Milk fat globule membrane as a nutritive substance in infant formula products) Variation</i> and ending 15 months after that date.
-------------------------------------------------------------	--------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Food Standards (Application A1308 – 2'-FL from GM *Escherichia coli* W 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 10 July 2025



Christel Leemhuis, General Manager, Public Health
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 180 on 22 July 2025. 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 A1308 – 2'-FL from GM Escherichia coli W 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:

2'-fucosyllactose sourced from *Escherichia coli* W section S3—54

[2] After section S3—53

Insert:

S3—54 Specification for 2'-fucosyllactose sourced from *Escherichia coli* W

For 2'-fucosyllactose (2'-FL) sourced from *Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae*, 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) molecular weight—488.44 g/mol;
- (d) CAS number—41263-94-9;
- (e) description—white to off-white powder;
- (f) 2'-FL—not less than 82% (water free);
- (g) D-lactose—not more than 5.0% (water free);
- (h) L-fucose—not more than 1.0% (water free);
- (i) fucosylgalactose—not more than 3.0% (water free);
- (j) difucosyllactose (difucosyl-d-lactose)—not more than 3.0% (water free);
- (k) glucose and galactose—not more than 1.0% (water free);
- (l) water—not more than 9.0%;
- (m) ash, sulphated—not more than 0.5%;
- (n) residual proteins—not more than 0.01%;
- (o) lead—not more than 0.1 mg/kg;
- (p) arsenic—not more than 0.1 mg/kg;
- (q) cadmium—not more than 0.1 mg/kg;
- (r) mercury—not more than 0.1 mg/kg;
- (s) microbiological:
 - (i) aerobic mesophilic bacteria total count—not more than 1,000 cfu/g;
 - (ii) yeasts and moulds—not more than 100 cfu/g;
 - (iii) *Enterobacteriaceae*—absent in 10 g;
 - (iv) residual endotoxins—not more than 10 EU/g.

Schedule 26—Food produced using gene technology

[3] Subsection S26—3(7) (table, table item 1)

Insert:

(f) *Escherichia coli* W
containing the gene for
alpha-1,2-
fucosyltransferase
from *Helicobacter mustelae*

1. May only be added to infant formula products.
2. During the exclusive use period, may only be sold under the brand 2'-FL Kyowa.
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 A1308 - 2'-FL from GM Escherichia coli W in infant formula products) Variation* and ending 15 months after that date.

Food Standards (Application A1310 – Food derived from insect-protected soybean line MON94637) 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 10 July 2025



Matthew O'Mullane, General Manager, Food Safety
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 180 on 22 July 2025. 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 A1310 – Food derived from insect-protected soybean line MON94637) 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:

(t) insect-protected soybean line MON94637

Food Standards (Application A1311 – Prolyl oligopeptidase from GM *Trichoderma reesei* as a processing aid) 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 10 July 2025



Matthew O'Mullane, General Manager, Food Safety
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 180 on 22 July 2025. 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 A1311 – Prolyl oligopeptidase from GM Trichoderma reesei 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:

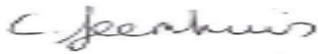
Prolyl oligopeptidase (EC 3.4.21.26) For use in brewing
sourced from *Trichoderma reesei*
containing the prolyl oligopeptidase
gene from *Aspergillus niger*

GMP

Food Standards (Proposal P1064 – Australian only Infant Formula Product Standard) 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 10 July 2025



Christel Leemhuis, General Manager, Public Health
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. . FSC 180 on 22 July 2025. 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 (Proposal P1064 – Australian only Infant Formula Product Standard) 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 1.1.1 – Structure of the Code and general provisions

[1] Subsection 1.1.1—2(2)

Omit:

Standard 2.9.1 Infant formula products

Substitute:

Standard 2.9.1 Infant formula products

Note Applies in Australia only

[2] Note 1 to Subsection 1.1.1—3(1)

Omit:

(vii) Chapter 3 (food safety standards) and Chapter 4 (primary production and processing standards).

Substitute:

(vii) Standard 2.9.1 (infant formula products);

(viii) Chapter 3 (food safety standards);

(vix) Chapter 4 (primary production and processing standards).

Standard 2.9.1 – Infant Formula Products

[3] Note 2 to the title of the Standard

Repeal the Note, substitute:

Note 2 This Standard applies in Australia only. New Zealand has under Annex D of the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* opted out of this Standard. See also section 1.1.1—3.