



Amendment No. 225

The following instruments are separate instruments in the Federal Register of Legislation and are known collectively in the Food Standards Gazette as Amendment No. 225

Table of contents

- **Food Standards (Application A1243 – Harmonisation of marine biotoxin standards for bivalve shellfish) Variation**
- **Food Standards (Application A1250 – Pullulanase from GM *Bacillus subtilis* (gene donor: *Bacillus deramificans*) as a processing aid) Variation**
- **Food Standards (Application A1267 – Fructanase from GM *Trichoderma reesei* as a processing aid) Variation**
- **Food Standards (Application A1268 – Steviol glycosides produced by bioconversion using new enzymes produced by GM *Escherichia coli*) Variation**

Food Standards (Application A1243 – Harmonisation of marine biotoxin standards for bivalve shellfish) 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.

12 January 2024



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 165 on 19 January 2024. 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 A1243 – Harmonisation of marine biotoxin standards for bivalve shellfish) 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.

4. Effect of the variations made by this instrument

- (1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.
- (2) During the transition period, a food product may be sold if the product complies with one of the following:
 - (a) the Code as in force without the variations made by this instrument; or
 - (b) the Code as amended by the variations made by this instrument.
- (3) For the purposes of this clause, ***transition period*** means the period commencing on the instrument's date of commencement and ending 12 months after the date of commencement.

Schedule

Schedule 19—Maximum levels of contaminants and natural toxicants

- [1] Section S19—5 (cell at table item dealing with “Diarrhetic shellfish poisons (Okadaic acid equivalent)”, column headed “Maximum level”)**

Repeal the cell, substitute:

0.16

- [2] Section S19—5 (cell at table item dealing with “Paralytic shellfish poisons (Saxitoxin equivalent)”, column headed “Contaminant”)**

Repeal the cell, substitute:

Paralytic shellfish poisons (Saxitoxin dihydrochloride equivalent)

Food Standards (Application A1250 – Pullulanase from GM *Bacillus subtilis* (gene donor: *Bacillus deramificans*) 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.

12 January 2024



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 165 on 19 January 2024. 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 A1250 – Pullulanase from GM Bacillus subtilis (gene donor: Bacillus deramificans) 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:

Pullulanase (EC 3.2.1.41) sourced from *Bacillus subtilis* containing the pullulanase gene from *Bacillus deramificans*

For use in starch processing for production of glucose syrups and other starch hydrolysates

GMP

Food Standards (Application A1267 – Fructanase 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.

12 January 2024



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 165 on 19 January 2024. 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 A1267 – Fructanase 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:

Fructan β -fructosidase, protein engineered variant, (EC 3.2.1.80) sourced from <i>Trichoderma reesei</i> containing the fructan β -fructosidase gene from <i>Lactobacillus crispatus</i>	For use in the manufacture of bakery products	GMP
---	---	-----

[2] Subsection S18—9(3) (note after table)

Omit the dot point list of protein engineered variants of enzymes in the note, substitute:

- Endo-1,4- β -xylanase, protein engineered variant;
- Fructan β -fructosidase, protein engineered variant;
- Glucoamylase, protein engineered variant;
- Maltogenic α -amylase, protein engineered variant;
- Protein engineered enzymes used in the manufacture of various steviol glycosides.

Food Standards (Application A1268 – Steviol glycosides produced by bioconversion using new enzymes produced by GM *Escherichia coli*) 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.

12 January 2024



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 165 on 19 January 2024. 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 A1268 – Steviol glycosides produced by bioconversion using new enzymes produced by GM Escherichia coli) 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] Subparagraph S3—35(2)(d)(ii)

Omit the subparagraph, substitute:

- (ii) is sourced from *Pichia pastoris* strain UGT-A;
- (e) by enzymatic conversion of purified stevia leaf extract to produce rebaudioside M using all of the following protein engineered enzymes:
 - (i) UTP-glucose-1-phosphate uridylyltransferase (EC 2.7.7.9) sourced from *Escherichia coli* K-12; and
 - (ii) UDP-glucosyltransferase sourced from *Escherichia coli* K-12; and
 - (iii) sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli* K-12;
- (f) by enzymatic conversion of purified stevia leaf extract to produce rebaudioside I using both of the following protein engineered enzymes:
 - (i) UTP-glucose-1-phosphate uridylyltransferase (EC 2.7.7.9) sourced from *Escherichia coli* K-12; and
 - (ii) sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli* K-12.

Schedule 18—Processing aids

[2] Subsection S18—9(3) (table)

Insert the following entry for each enzyme in alphabetical order:

Sucrose synthase, protein engineered variant, (EC 2.4.1.13) sourced from <i>Escherichia coli</i> K-12 containing the gene for sucrose synthase from <i>Glycine max</i>	For the conversion of purified stevia leaf extract to produce one or more of the following: rebaudioside I and rebaudioside M	GMP
Uridine diphosphate (UDP)-glucosyltransferase, protein engineered variant, sourced from <i>Escherichia coli</i> K-12 containing the UDP-glucosyltransferase gene from <i>Oryza sativa</i>	For the conversion of purified stevia leaf extract to produce rebaudioside M	GMP
Uridine triphosphate (UTP)-glucose-1-phosphate uridylyltransferase, protein engineered variant, (EC 2.7.7.9) sourced from <i>Escherichia coli</i> K-12, containing the gene for UTP-glucose-1-phosphate uridylyltransferase from <i>Bifidobacterium bifidum</i>	For the conversion of purified stevia leaf extract to produce one or more of the following: rebaudioside I and rebaudioside M	GMP