

AUSTRALIA NEW ZEALAND FOOD AUTHORITY

VARIATIONS TO THE *FOOD STANDARDS CODE*

(AMENDMENT No. 54)

1. Preamble

The variations set forth in the Schedule below are variations to the *Food Standards Code* (hereinafter called 'the Code') which was published by the National Health and Medical Research Council in the *Commonwealth of Australia Gazette*, No. P 27, on 27 August 1987, and which has been varied from time to time.

The Schedule contains variations adopted by the Australia New Zealand Food Standards Council in March and June 2001.

These variations are published pursuant to section 32 of the *Australia New Zealand Food Authority Act 1991*.

2. Citation

These variations may be collectively known as *Amendment No. 54* to the Code.

3. Commencement

These variations commence on the date of gazettal.

SCHEDULE

[1] *Standard A11 is varied by -*

[1.1] *inserting immediately following paragraph (1)(u) -*

(v) Addendum 8 means *Addendum 8* to this Standard.;

[1.2] *inserting in columns 1 and 2 respectively of the Schedule, immediately following the entry for Bromelain, the entries listed in column 1 and column 2 as set out below -*

Column 1	Column 2
Substance	Reference to Specification
Bromo-chloro-dimethylhydantoin	Addendum 8

[1.3] *inserting immediately after Addendum 7 -*

ADDENDUM 8

SPECIFICATIONS FOR BROMO-CHLORO-DIMETHYLHYDANTOIN

Bromo-chloro-dimethylhydantoin (CAS Number: 126-06-7)

Formula:	C ₅ H ₆ BrClN ₂ O ₂
Formula weight:	41.5
<u>Chemical Properties</u>	
Appearance:	Solid or free flowing granules
Colour:	White
Odour:	Faint halogenous odour
Melting Point	163-164 ⁰ C
Specific gravity	1.8-2
Solubility in water	0.2g/100g at 25°C
Stability	Stable when dry and uncontaminated

Chemical Tests:

Manufacturing process: Solid dimethylhydantoin (DMH) is dissolved in water with bromine and chlorine. The reaction is 0.5 mole bromine and 1.5 mole chlorine for one mole DMH. During the reaction the pH is kept basic by the addition of caustic soda. The wet product is transferred to a drier where it is dried to a powder at low temperature. The powder may then be tableted or granulated.

Assay:

Procedure: Various analytical methods exist for analysis, namely, GLC, HPLC, UV and NMR. HPLC offers the best sensitivity.

[1.4] *inserting immediately after ADDENDUM 8, the following –*

ADDENDUM 9

SPECIFICATION FOR PHYTOSTEROL ESTERS DERIVED FROM VEGETABLE OILS

Phytosterol esters are phytosterols derived from edible vegetable oils esterified with long-chain fatty acids derived from edible vegetable oils.

Phytosterol esters + free phytosterols (%)	min.	94		
Free phytosterols (%)	max.	10		
Steradienes (%)	max.	0.3		
Fatty acid methylester (%)	max.	0.5		
Iron, Fe (ppm)	max.	1.0		
Copper, Cu (ppm)	max.	0.5		
Moisture (%)	max.	0.1		
Trans fatty acids (%)	max.	1.0		
Sterol profile (%) as below -				
Cholesterol	min.	0.0	max.	2.0
Brassicasterol	min.	0.0	max.	6.0
Campesterol	min.	20.0	max.	29.0
Campestanol	min.	0.0	max.	6.0
Stigmasterol	min.	12.0	max.	23.0

β-Sitosterol	min.	42.0	max.	55.0
β-Sitostanol	min.	0.0	max.	2.5
D5-Avenasterol	min.	0.0	max.	4.0
D7-Stigmastenol	min.	0.0	max.	2.0
D7-Avenasterol	min.	0.0	max.	2.0
Other	min.	0.0	max.	6.0

[2] *Standard A16 is varied by inserting in the Group II, Table II, the entries listed in column 1 and column 2 respectively as set out below -*

Column 1	Column 2
Substance	Maximum permitted residue (mg/kg)
Bromo-chloro-dimethylhydantoin	1.0 (available chlorine) 1.0 (inorganic bromide) 2.0 (dimethylhydantoin)

[3] *Standard A19 is varied by deleting the Table to clause 2, substituting –*

Table to clause 2

Column 1	Column 2
Novel Food	Conditions of Use
phytosterol esters	<p>May only be added to food -</p> <p>(1) according to Standard G2 or G5 and Standard A11; and</p> <p>(2) where the total fatty acid present in the food is not more than 280 g/kg of saturated fatty acids.</p> <p>The name ‘phytosterol ester or plant sterol esters’ must be used when declaring the ingredient in the ingredient list, as prescribed in clause 5 of Standard A1.</p> <p>The label on or attached to a package of food containing phytosterol esters must include statements to the effect that -</p> <ol style="list-style-type: none"> the product should be consumed in moderation as part of a diet low in saturated fats and high in fruit and vegetables; the product is not recommended for infants, children and pregnant or lactating women unless under medical supervision; and consumers on cholesterol-lowering medication should seek medical advice on the use of this product in conjunction with their medication.

[4] *Standard G2 is varied by-*

[4.1] *deleting after subparagraph (1)(b)(ii)(H), the following –*

(I) not more than 5 g/kg of polyglycerol esters of fatty acids.

[4.2] *inserting immediately after subparagraph (1)(b)(ii)(H), the following –*

- (I) not more than 5 g/kg of polyglycerol esters of fatty acids;
- (J) not more than 137 g/kg of phytosterol esters.

[5] *Standard G5 is varied by -*

[5.1] *deleting after paragraph 2(3)(m), the following -*

- (n) starch.

[5.2] *inserting immediately after paragraph 2(3)(m), the following –*

- (n) starch;
- (o) not more than 137 g/kg of phytosterol esters.

[6] *Standard 1.2.3 is varied by inserting into Columns 1 and 2 respectively of the Table to clause 2, the following –*

Food regulated in Standard 2.4.2 containing phytosterol esters.	<p>Statements to the effect that -</p> <ol style="list-style-type: none"> 1. the product should be consumed in moderation as part of a diet low in saturated fats and high in fruit and vegetables; 2. the product is not recommended for infants, children and pregnant or lactating women unless under medical supervision; and 3. consumers on cholesterol-lowering medication should seek medical advice on the use of this product in conjunction with their medication.
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[7] *Standard 1.3.3 is varied by inserting in the Table to clause 12, immediately following the entry for Benzoyl peroxide, the following entries listed below -*

Substance	Food	Maximum permitted residue (mg/kg)
Bromo-chloro-dimethylhydantoin	All foods	1.0 (available chlorine) 1.0 (inorganic bromide) 2.0 (dimethylhydantoin)

[8] *Standard 1.3.4 is varied by -*

[8.1] *inserting in the Schedule, immediately following the entry for oxidised polyethylene-*

Specification for Bromo-chloro-dimethylhydantoin

Bromo-chloro-dimethylhydantoin (CAS Number: 126-06-7)

Formula: $C_5H_6BrClN_2O_2$
 Formula weight: 241.5

Chemical Properties

Appearance:	Solid or free flowing granules
Colour:	White
Odour:	Faint halogenous odour
Melting Point	163-164 ⁰ C
Specific gravity	1.8-2
Solubility in water	0.2g/100g at 25°C
Stability	Stable when dry and uncontaminated

Chemical Tests:

Manufacturing process: Solid dimethylhydantoin (DMH) is dissolved in water with bromine and chlorine. The reaction is 0.5 mole bromine and 1.5 mole chlorine for one mole DMH. During the reaction the pH is kept basic by the addition of caustic soda. The wet product is transferred to a drier where it is dried to a powder at low temperature. The powder may then be tableted or granulated.

Assay:

Procedure: Various analytical methods exist for analysis, namely, GLC, HPLC, UV and NMR. HPLC offers the best sensitivity.

[8.2] *inserting immediately after* Testing Requirements for Nucleotides – Item 9
Bacteriological profile, *the following* –

Specification for phytosterol esters derived from vegetable oils

Phytosterol esters are phytosterols derived from edible vegetable oils esterified with long-chain fatty acids derived from edible vegetable oils.

Phytosterol esters + free phytosterols (%)	min.	94	
Free phytosterols (%)		max.	10
Steradienes (%)		max.	0.3
Fatty acid methylester (%)		max.	0.5
Iron, Fe (ppm)		max.	1.0
Copper, Cu (ppm)		max.	0.5
Moisture (%)		max.	0.1
Trans fatty acids (%)		max.	1.0
Sterol profile (%) as below -			
Cholesterol	min.	0.0	max. 2.0
Brassicasterol	min.	0.0	max. 6.0
Campesterol	min.	20.0	max. 29.0
Campestanol	min.	0.0	max. 6.0
Stigmasterol	min.	12.0	max. 23.0
β-Sitosterol	min.	42.0	max. 55.0
β-Sitostanol	min.	0.0	max. 2.5
D5-Avenasterol	min.	0.0	max. 4.0
D7-Stigmastenol	min.	0.0	max. 2.0
D7-Avenasterol	min.	0.0	max. 2.0
Other	min.	0.0	max. 6.0

[9] *Standard 1.5.1 is varied by deleting the Table to clause 2, substituting* –

Table to clause 2

Column 1	Column 2
Novel Food	Conditions of Use
phytosterol esters	<p>The requirements in clause 2 of Standard 1.2.3.</p> <p>The name 'phytosterol ester or plant sterol esters' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4.</p> <p>May only be added to food -</p> <p>(1) according to Standards 1.3.4 and 2.4.2; and</p> <p>(2) where the total saturated and trans fatty acids present in the food is no more than 28% of the total fatty acid content of the food.</p>

[10] *Standard 2.4.2 is varied by inserting immediately after paragraph 2(1)(f), the following –*

- (g) no more than 137 g/kg of phytosterol esters.