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AUSTRALIA NEW ZEALAND

FOOD AUTHORITY

AMENDMENT NO. 132
TO THE FOOD STANDARDS CODE

AUSTRALIA NEW ZEALAND FOOD AUTHORITY

VARIATIONS TO THE *FOOD STANDARDS CODE*

AMENDMENT NO. 132

The following instruments are separate instruments in the Federal Register of Legislative Instruments and are known collectively in the Food Standards Gazette as Amendment No. 132.

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FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Standard 2.9.5 – Food for Special Medical Purposes

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on 28 June 2014.

Dated 22 June 2012

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

STANDARD 2.9.5

FOOD FOR SPECIAL MEDICAL PURPOSES

Purpose

This Standard regulates the sale, composition and labelling of foods specially formulated for the dietary management of individuals with certain diseases, disorders or medical conditions. Food regulated by this Standard is intended to be used under medical supervision.

Because of the specialised nature and purpose of these foods, this Standard includes a restriction on the premises at which, and the persons by whom, food for special medical purposes may be sold to consumers.

Infant formula products as defined in Standard 2.9.1 of the Code and products formulated and represented as being for the dietary management of obesity or overweight are excluded from Standard 2.9.5, even though they might meet the requirements of this Standard.

Editorial note:

In accordance with usual practice, this Standard must be read in the context of the whole Code. This Standard both incorporates and exempts existing Standards in the Code, and also applies additional requirements specifically for food for special medical purposes. Where existing requirements have been incorporated, these are replicated in the Standard rather than cross referenced to the original Standard, for accuracy and ease of use.

Table of Provisions

Clauses

Division 1 – Preliminary

1 Definition of food for special medical purposes

(1) Subject to subclause (2), a food is a food for special medical purposes if the food is –

(a) specially formulated for the dietary management of individuals –

(i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and

(ii) whose dietary management cannot be completely achieved without the use of the food; and

(b) intended to be used under medical supervision; and

(c) represented as being a food for special medical purposes or for the dietary management of a disease, disorder or medical condition.

(2) A food is not a food for special medical purposes if the food is –

(a) formulated and represented as being for the dietary management of obesity or overweight; or

(b) an infant formula product as defined in Standard 2.9.1.

Example:

An infant formula product specifically formulated to satisfy metabolic conditions (refer Subdivision 2 of Division 3 of Standard 2.9.1) is excluded from the definition of a food for special medical purposes, even if the infant formula product satisfies the requirements of paragraphs (1)(a),(b) and (c), and will not be regulated by Standard 2.9.5.

2 Other definitions

(1) In this Standard –

inner package, in relation to a food for special medical purposes, means an individual package of the food that –

(a) is contained and sold within another package that is labelled in accordance with Subdivision 2 of Division 4; and

(b) is not designed for individual sale, other than a sale by a responsible institution to a patient or resident of the responsible institution.

Example:

An example of an inner package is an individual sachet (or sachets) of a powdered food contained within a box that is fully labelled, being a box available for retail sale.

responsible institution means a hospital, hospice, aged care facility, disability facility, prison, boarding school or similar institution that is responsible for the welfare of its patients or residents and provides food to them.

(2) In this Standard, a reference to a **package** does not include a plate, cup, tray or other food container in or on which food for special medical purposes is served by a responsible institution to a patient or resident of the responsible institution, whether the plate, cup, tray or food container is uncovered, or is covered in whole or in part.

3 Application of other Standards

(1) The following do not apply to a food for special medical purposes –

(a) clause 9 of Standard 1.1.1;
(b) Standards 1.1A.2, 1.3.2 and 1.5.1;
(c) Standards 2.9.2, 2.9.3 and 2.9.4;
(d) Part 1.2 of this Code, subject to subparagraph 9(e) (iv), paragraph 12(a), clauses 13 and 16, and sub clauses 17(3), (4) and (5).

(2) Subclauses 6(3) and (4) of Standard 1.5.3 apply to a food for special medical purposes as if such food were subject to Standard 1.2.1.

4 Claims must not be therapeutic in nature

A claim in relation to a food for special medical purposes must not –

(a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or
(b) compare the food with a good that is –

(i) represented in any way to be for therapeutic use; or
(ii) likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason.

Division 2 – Sale of food for special medical purposes

5 Restriction on the persons by whom, and the premises at which, food for special medical purposes may be sold

(1) A food for special medical purposes must not be sold to a consumer, other than from or by –

(a) a medical practitioner or dietitian; or
(b) a medical practice, pharmacy or responsible institution; or
(c) a majority seller of that food for special medical purposes.

(2) In this clause, **medical practitioner** means a person registered or licensed as a medical practitioner under legislation in Australia or New Zealand, as the case requires, for the registration or licensing of medical practitioners.

(3) In this clause, a person is a **majority seller** of a food for special medical purposes during any [24] month period if –

(a) during the period, the person sold that food for special medical purposes to medical practitioners, dietitians, medical practices, pharmacies or responsible institutions; and
(b) the sales mentioned in paragraph (a) represent more than one half of the total quantity of that food for special medical purposes sold by the person during the period.

Division 3 – Composition

6 Permitted forms of particular substances

(1) All or any of the following substances may be added to a food for special medical purposes –

(a) a substance that is listed in Column 1 of Schedule 1 of this Standard if the substance is in one or more of the corresponding forms listed in Column 2 of that Schedule;
(b) a substance that is listed in Column 1 of Schedule 1 of Standard 2.9.1 if the substance is in one or more of the corresponding forms listed in Column 2 of that Schedule;
(c) any other substance regardless of its form, subject to the requirements of any Standard that applies to the substance or the food for special medical purposes.

(2) A provision in another Standard that limits the amount of a substance mentioned in paragraph (1)(a) or (b) that may be added to a food does not apply to a food for special medical purposes.

7 Compositional requirements for food represented as being suitable for use as a sole source of nutrition

(1) If a food for special medical purposes is represented as being suitable for use as a sole source of nutrition, the food must contain –

(a) not less than the minimum amount, as prescribed in Column 2 of Schedule 2, of each vitamin, mineral and electrolyte contained in Column 1 of that Schedule; and
(b) if applicable, not more than the maximum amount, as prescribed in Column 3 of Schedule 2, of each vitamin and mineral contained in Column 1 of that Schedule.

(2) However, the food is not required to comply with subclause (1) to the extent that –

(a) a variation from a maximum or minimum amount is required for a particular medical purpose; and
(b) the food is labelled in accordance with subclause 10(2).

Division 4 – Labelling
Subdivision 1 – Outline of requirements

8 Labelling and related requirements

(1) There must be a label on a package of food for special medical purposes.

(2) Subject to sub clauses (3) and (4), the label must comply with the requirements of Subdivision 2.

(3) The requirements of Subdivision 3 apply instead of Subdivision 2 if the package is an inner package.

(4) The requirements of Subdivision 4 apply instead of Subdivision 2 to transportation outer.

(5) To avoid doubt, this Division does not apply to a food for special medical purposes that is not in a package.

Subdivision 2 – General labelling requirements

9 Mandatory information

The label on a package of food for special medical purposes must include the following information –

(a) a name or a description of the food sufficient to indicate the true nature of the food;
(b) the lot identification of the food;
(c) directions for the use of the food or the storage of the food, or both, if the food is of such a nature to require directions for health or safety reasons;
(d) the minimum or average energy content expressed per given quantity of the food;
(e) the average quantity or minimum quantity, expressed per given quantity of the food, of –

(i) protein, fat and carbohydrate; and
(ii) any vitamin, mineral or electrolyte present in the food, if the vitamin, mineral or electrolyte has been added to the food; and
(iii) any substance present in the food, if that substance is listed under Column 1 of Schedule 1 and has been added to the food; and
(iv) subject to sub clauses 14(4) and 15(5) of this Standard, any other substance if a nutrition claim as defined in Standard 1.2.8 is made in relation to that substance.

10 Mandatory statements

(1) The label on a package of food for special medical purposes must include the following statements –

(a) a statement to the effect that the food must be used under medical supervision;
(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food;
(c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated;
(d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph (c);
(e) if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group;
(f) a statement indicating whether or not the food is suitable for use as a sole source of nutrition;
(g) the statements required by subclause (2) if the food is represented as being suitable for use as a sole source of nutrition;
(h) the advisory statements required by subclause (3);
(i) the warning statement required by subclause (4).

(2) For paragraph (1)(g), the required statements are –

(a) a statement to the effect that the food is not for parenteral use; and
(b) if the food has been modified to vary from the compositional requirements in Schedule 2 such that the content of one or more nutrients falls short of the prescribed minimum, or exceeds the prescribed maximum (if applicable), a statement indicating –

(i) the nutrient or nutrients which have been modified; and
(ii) whether each modified nutrient has been increased, decreased, or eliminated from the food.

(3) For paragraph (1)(h), the required advisory statements are –

(a) if the food contains bee pollen as an ingredient as defined in Standard 1.2.4—a statement to the effect that the food contains bee pollen which can cause severe allergic reactions; and
(b) if the food contains aspartame or aspartame-acesulphame salt—a statement to the effect that the food contains phenylalanine; and
(c) if the food contains guarana or extracts of guarana—a statement to the effect that the food contains caffeine; and
(d) if the food contains propolis as an ingredient as defined in Standard 1.2.4—a statement to the effect that the food contains propolis which can cause severe allergic reactions; and
(e) a statement to the effect that excess consumption of the food may have a laxative effect if the food contains –
(i) one or more of the substances listed in Table 1 to this paragraph, either singularly or in combination, at a level of or in excess of 10 g/100 g; or
(ii) one or more of the substances listed in Table 2 to this paragraph, either singularly or in combination, at a level of or in excess of 25 g/100 g; or
(iii) one or more of the substances listed in Table 1, in combination with one or more of the substances listed in Table 2, at a level of or in excess of 10 g/100 g.

Table 1 to paragraph

Substance
Lactitol
Maltitol
Maltitol syrup
Mannitol
Xylitol

Table 2 to paragraph

Substance
Erythritol
Isomalt
Polydextrose
Sorbitol

(4) If a food for special medical purposes contains royal jelly as an ingredient as defined in Standard 1.2.4, the following warning statement is required –

"This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases, fatalities, especially in asthma and allergy sufferers".

Editorial note:

The requirements of sub clauses 10(3) and (4) are based on relevant aspects of clauses 2, 3 and 5 of Standard 1.2.3.

(5) Despite paragraph (1)(g), the information mentioned in subparagraph (2)(b)(ii) is not required to be on the label if the information is provided in other documentation about the food for special medical purposes.

11 Mandatory declaration

(1) A declaration of the presence in a food for special medical purposes of any of the substances listed in the Table to this clause is required if the substance is present as –

(a) an ingredient; or
(b) an ingredient of a compound ingredient; or
(c) a food additive or component of a food additive; or
(d) a processing aid or component of a processing aid.

Table to subclause 11(1)

Added Sulphites in concentrations of 10 mg/kg or more
Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains
Crustacea and their products
Egg and egg products
Fish and fish products
Milk and milk products
Peanuts and peanut products
Sesame seeds and sesame seed products
Soybeans and soybean products
Tree nuts and tree nut products other than coconut from the fruit of the palm Cocos nucifera

(2) If a declaration in relation to a food for special medical purposes is required under subclause (1), the declaration must be included on the label on any package of the food.

Editorial note:

The requirement of clause 11 is based on clause 4 of Standard 1.2.3.

12 Labelling of ingredients

The label on a package of food for special medical purposes must comply with one of the following –

(a) Standard 1.2.4 of this Code;
(b) Article 6, Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs;
(c) 21 CFR § 101.4.

13 Date marking of food

(1) A food for special medical purposes must comply with Standard 1.2.5.

(2) However, if a label on a package of food for special medical purposes is required to include a use-by date under Standard 1.2.5, the words 'Expiry Date', or words to similar effect, may be used instead of the words 'Use By', and Standard 1.2.5 applies to the food for special medical purposes as if any reference to a use-by date in that Standard were a reference to the 'Expiry Date', or the words to similar effect so used.

14 Lactose claims in relation to food for special medical purposes

(1) A claim to the effect that a food for special medical purposes is lactose free may be made if the food contains no detectable lactose.

(2) A claim to the effect that a food for special medical purposes is low lactose may be made if the food contains not more than 0.3 g of lactose per 100 g of the food.

(3) A claim to the effect that a food for special medical purposes is lactose reduced must be accompanied by a declaration of the proportion by which the lactose content of the food has been reduced.

(4) If a claim is made in relation to the lactose content of a food for special medical purposes, the label on the package of food must include the average quantity of the lactose and galactose in the food, expressed per given quantity of the food.

Editorial note:

The requirement of clause 14 is based on clause 15 of Standard 1.2.8.

15 Claims in relation to gluten content of food for special medical purposes

(1) A claim in relation to the gluten content of a food for special medical purposes is prohibited unless expressly permitted by this clause.

(2) A claim to the effect that a food for special medical purposes is gluten free may be made if the food contains –

(a) no detectable gluten; and
(b) no oats or oat products; and
(c) no cereals containing gluten that have been malted, or products of such cereals.

(3) A claim to the effect that a food for special medical purposes has a low gluten content may be made if the food contains no more than 20 mg gluten per 100 g of the food.

(4) A claim to the effect that a food for special medical purposes contains gluten or is high in gluten may be made.

(5) If a claim is made in relation to the gluten content of a food for special medical purposes, the label on the package of food must include the average quantity of the gluten in the food, expressed per given quantity of the food.

Editorial note:

The requirement of clause 15 is based on clause 16 of Standard 1.2.8.

16 Legibility requirements

The label on a package of food for special medical purposes must comply with Standard 1.2.9.

Subdivision 3 – Labelling requirements for inner packages

17 Labelling requirements for inner packages

(1) There must be a label on an inner package of food for special medical purposes.

(2) The label must include –

(a) a name or a description of the food sufficient to indicate the true nature of the food; and
(b) the lot identification of the food; and
(c) a declaration of the presence in the food of any of the substances listed in the Table to this paragraph if the substance is present as –

(i) an ingredient; or
(ii) an ingredient of a compound ingredient; or
(iii) a food additive or component of a food additive; or
(iv) a processing aid or component of a processing aid.

Table to paragraph

Added Sulphites in concentrations of 10 mg/kg or more
Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains
Crustacea and their products
Egg and egg products
Fish and fish products
Milk and milk products
Peanuts and peanut products
Sesame seeds and sesame seed products
Soybeans and soybean products
Tree nuts and tree nut products other than coconut from the fruit of the palm Cocos nucifera

(3) A food for special medical purposes contained in an inner package must comply with Standard 1.2.5, other than clause 6 of that Standard.

(4) However, if a label on an inner package of food for special medical purposes is required to include a use-by date under Standard 1.2.5, the words 'Expiry Date', or words to similar effect, may be used instead of the words 'Use By', and Standard 1.2.5 applies to the food for special medical purposes as if any reference to a use-by date in that Standard were a reference to the 'Expiry Date', or the words to similar effect so used.

(5) The label on an inner package of food for special medical purposes must comply with Standard 1.2.9.

(6) To avoid doubt, this clause continues to apply to the label on an inner package of food for special medical purposes even if a responsible institution subsequently supplies the inner package to a patient or resident of the responsible institution.

Editorial note:

The requirement of paragraph 17(2)(c) is based on the requirements of clause 4 of Standard 1.2.3.

Subdivision 4 – Information requirements for transportation outers

18 Information required on transportation outers

(1) If packages of food for special medical purposes are in a transportation outer, then there must be a label on the transportation outer that includes –

(a) a name or a description of the food sufficient to indicate the true nature of the food; and
(b) the lot identification of the food; and

(c) the name and business address in Australia or New Zealand of the supplier of the food, unless that information is provided in documentation accompanying the food for special medical purposes.

(2) However, a label on a transportation outer is not required if the information mentioned in paragraphs (1)(a), (b) and (c) is clearly discernible through the transportation outer on the labels on the packages within the transportation outer.

SCHEDULE 1
Permitted forms of particular substances

Column 1	Column 2
Substances	**Permitted Form**
Vitamins	
Niacin	Nicotinic acid
Vitamin B_6	Pyridoxine dipalmitate
Folate	Calcium L-methylfolate
Vitamin E	D-alpha-tocopherol
	D-alpha-tocopheryl polyethylene glycol-1000 succinate (TPGS)
Pantothenic acid	Sodium pantothenate
	D-panthenol
	DL-panthenol
Minerals and Electrolytes	
Boron	Sodium borate
	Boric acid
Calcium	Calcium bisglycinate
	Calcium citrate malate
	Calcium malate
	Calcium L-pidolate
Chloride	Choline chloride
	Sodium chloride, iodised
	Hydrochloric acid
Chromium	Chromium chloride
	Chromium picolinate
	Chromium potassium sulphate
Copper	Copper-lysine complex
	Cupric carbonate
Fluoride	Potassium fluoride
	Sodium fluoride
Iodine	Sodium iodate
Iron	Carbonyl iron
	Electrolytic iron
	Ferric citrate
	Ferric gluconate
	Ferric orthophosphate
	Ferric pyrophosphate, sodium
	Ferric saccharate
	Ferric sodium diphosphate
	Ferrous bisglycinate
	Ferrous carbonate
	Ferrous carbonate, stabilised
	Ferrous L-pidolate
	Iron, reduced (ferrum reductum)
Magnesium	Magnesium acetate
	Magnesium L-aspartate
	Magnesium bisglycinate
	Magnesium citrate
	Magnesium glycerophosphate
	Magnesium hydroxide
	Magnesium hydroxide carbonate
	Magnesium lactate
	Magnesium phosphate, monobasic
	Magnesium L-pidolate
	Magnesium potassium citrate
Manganese	Manganese glycerophosphate
Molybdenum	Ammonium molybdate
Potassium	Potassium glycerophosphate
	Potassium lactate
	Potassium L-pidolate
Selenium	Selenium enriched yeast
	Sodium hydrogen selenite
	Sodium selenate

SCHEDULE 1 (continued)
Permitted forms of particular substances

Column 1	Column 2
Substances	**Permitted Form**
Zinc	Zinc bisglycinate
	Zinc carbonate
	Zinc citrate
	Zinc lactate
Other substances	
Amino acids	Sodium, potassium, calcium, magnesium salts of single amino acids listed in this Schedule
	Hydrochlorides of single amino acids listed in this Schedule
	L-alanine
	L-arginine
	L-asparagine
	L-aspartic acid
	L-citrulline
	L-cysteine
	L-cystine
	L-glutamic acid
	L-glutamine
	Glycine
	L-histidine
	L-isoleucine
	L-leucine
	L-lysine
	L-lysine acetate
	L-methionine
	L-ornithine
	L-phenylalanine
	L-proline
	L-serine
	L-threonine
	L-tyrosine
	L-tryptophan
	L-valine
	L-arginine-L-aspartate
	L-lysine-L-aspartate
	L-lysine-L-glutamate
	N-acetyl-L-methionine
	L-carnitine
Carnitine	L-carnitine hydrochloride
	L-carnitine L-tartrate
	Choline
Choline	Choline bitartrate
	Choline chloride
	Choline citrate
	Choline hydrogen tartrate
	Inositol
Inositol	Adenosine 5′-monophosphate
Nucleotides	Adenosine 5′-monophosphate sodium salt
	Cytidine 5′-monophosphate
	Cytidine 5′-monophosphate sodium salt
	Guanosine 5′-monophosphate
	Guanosine 5′-monophosphate sodium salt
	Inosine 5′-monophosphate
	Inosine 5′-monophosphate sodium salt
	Uridine 5′-monophosphate
	Uridine 5′-monophosphate sodium salt
Taurine	Taurine

SCHEDULE 2
Minimum and maximum content of vitamins, minerals and electrolytes in food for special medical purposes represented as being suitable for use as a sole source of nutrition

Column 1	Column 2	Column 3
Nutrient	**Minimum Amount per MJ**	**Maximum Amount per MJ**
Vitamins		
Vitamin A	84 µg retinol equivalents[1]	430 µg retinol equivalents[1]
Thiamin	0.15 mg	No maximum set
Riboflavin	0.2 mg	No maximum set
Niacin	2.2 mg niacin equivalents[2]	No maximum set
Vitamin B_6	0.2 mg	1.2 mg
Folate	25 µg	No maximum set
Vitamin B_{12}	0.17 µg	No maximum set
Vitamin C	5.4 mg	No maximum set
Vitamin D	1.2 µg	6.5 µg or 7.5 µg[3]
Vitamin E	1 mg alpha-tocopherol equivalents[4]	No maximum set
Biotin	1.8 µg	No maximum set
Pantothenic Acid	0.35 mg	No maximum set
Vitamin K	8.5 µg	No maximum set
Minerals		
Calcium	84 mg or 120 mg[3]	420 mg or 600 mg[3]
Magnesium	18 mg	No maximum set
Iron	1.2 mg	No maximum set
Phosphorus	72 mg	No maximum set
Zinc	1.2 mg	3.6 mg
Manganese	0.12 mg	1.2 mg
Copper	0.15 mg	1.25 mg
Iodine	15.5 µg	84 µg
Chromium	3 µg	No maximum set
Molybdenum	7 µg	No maximum set
Selenium	6 µg	25 µg
Electrolytes		
Sodium	72 mg	No maximum set
Potassium	190 mg	No maximum set
Chloride	72 mg	No maximum set

[1, 2, and 4] These numbers refer to the corresponding numbers in the footnotes in Schedule 1 in Standard 1.1.1.

[3] The higher amount applies only to products intended for children aged one to ten years.

FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) 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 Standard commences on the date specified in clause 3 of this variation.

Dated 22 June 2012

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

This variation commences on 28 June 2014.

SCHEDULE

[1] ***Standard 1.1.1*** *is varied by –*

[1.1] *inserting in clause 2 the following definitions in alphabetical order –*

food for special medical purposes has the meaning given by Standard 2.9.5.

small package means a package with a surface area of less than 100 cm^2.

transportation outer means a container or wrapper which –

(a) encases packaged or unpackaged foods for the purpose of transportation and distribution; and
(b) is removed before the food is used or offered for retail sale, or is not taken away by the purchaser of the food.

[1.2] *omitting paragraph (e) from the definition of* **warning statement** *in clause 2, substituting –*

(e) sub clauses 3(3) and 3(4) of Standard 2.9.4; and
(f) subclause 10(4) of Standard 2.9.5.

[1.3] *inserting in alphabetical order in the* Table to clause 8 –

MJ	Megajoule

[2] ***Standard 1.1A.6*** *is varied by omitting subclause 2(3), substituting –*

(3) This Standard ceases to have effect on the date of commencement of Standard 2.9.5, other than in relation to food formulated and represented as being for the dietary management of obesity.

[3] ***Standard 1.2.1*** *is varied by omitting from clause 1 the definitions of* **small package** *and* **transportation outer**

[4] ***Standard 1.3.1*** *is varied by –*

[4.1] *omitting from* Schedule 1*, the heading to Item 13, substituting –*

13 SPECIAL PURPOSE FOODS

[4.2] *inserting in* Schedule 1 *after Item 13.4.2 –*

13.5 Food for special medical purposes*

200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	1500	mg/kg	
210 211 212 213	Benzoic acid and sodium, potassium and calcium benzoates	1500	mg/kg	
338	Phosphoric acid	GMP		Permitted for use as an acidity regulator

524	Sodium hydroxide	GMP		Permitted for use as an acidity regulator
525	Potassium hydroxide	GMP		Permitted for use as an acidity regulator
950	Acesulphame potassium	450	mg/kg	
954	Saccharin	200	mg/kg	
962	Aspartame-acesulphame salt	450	mg/kg	

13.5.1 Liquid food for special medical purposes*

123	Amaranth	30	mg/kg
160b	Annatto extracts	10	mg/kg

13.5.2 Food for special medical purposes other than liquids*

123	Amaranth	300	mg/kg
160b	Annatto extracts	25	mg/kg

[5] ***Standard 1.3.4*** *is varied by adding at the end of the* Schedule –

Specification selenium-enriched yeast

Selenium-enriched yeasts are produced by culture in the presence of sodium selenite as a source of selenium. These yeasts contain selenium according to the following criteria –

Total selenium content	No more than 2.5 mg/kg of the dried form as marketed
Levels of organic selenium species (% total extracted selenium):	
Selenomethionine	No less than 60% and no more than 85%
Other organic selenium compounds (including selenocysteine)	No more than 10%
Levels of inorganic selenium (% total extracted selenium)	No more than 1%

FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Food Standards (Proposal P1007 – Primary Production & Processing Requirements for Raw Milk 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 Standard commences on the date specified in clause 3 of this variation.

Dated 22 June 2012

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Proposal P1007 – Primary Production & Processing Requirements for Raw Milk Products) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

This variation commences on 28 June 2012.

SCHEDULE

[1] ***Standard 4.2.4*** *is varied by omitting clause 16, substituting –*

16 Processing of dairy products to make cheese and cheese products

(1) Milk used to make cheese or cheese products must be processed –

(a) in accordance with subclause 15(1); or
(b) by being held at a temperature of no less than 64.5°C for a period of no less than 16 seconds, and the cheese or cheese product stored at a temperature of no less than 7°C for a period of no less than 90 days from the date of processing.

(2) Dairy products used to make cheese or cheese products must be processed –

(a) in accordance with subclause 15(3); or
(b) using a heat treatment that uses a combination of time and temperature of equal or greater lethal effect on any pathogenic micro-organisms in the dairy product achieved by paragraph 16(1)(b).

(3) However, milk or dairy products used to make cheese or cheese products do not need to be processed in accordance with subclauses 16(1) and 16(2) if the cheese or cheese product is processed –

(a) such that –

(i) the curd is heated to a temperature of no less than 48°C; and
(ii) the cheese or cheese product has a moisture content of less than 39%, after being stored at a temperature of no less than 10°C for a period of no less than 120 days from the date of processing; or

(b) in accordance with clause 1 of Standard 4.2.4A.

[2] ***Standard 4.2.4A*** *is varied by –*

[2.1] *omitting from the* Table to clause 1 –

Gruyere, Sbrinz or Emmental cheese	The *Ordinance on Quality Assurance in the Dairy Industry* of the Swiss Federal Council of 18 October 1995	

[2.2] *omitting the* Editorial note *following clause 1, substituting* –

Editorial note:

Clause 4 of Standard 1.2.4 requires ingredients to be declared using the common name of the ingredient, or a name that describes the true nature of the ingredient, or if applicable a generic name. This requirement means that in relation to cheese made from unpasteurised milk, the ingredient declaration should include a statement that the milk is unpasteurised, and in the case of cheese made other than from cow's milk, should also include the common name of the species from which the milk is sourced.

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