#### 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**

Division 1 – Preliminary

- Definition of food for special medical purposes
- 2 Other definitions
- 2A Deemed compliance with Standard for certain periods
- 3 Application of other Standards
- 4 Claims must not be therapeutic in nature

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

Division 3 – Composition

- 6 Permitted forms of particular substances
- 7 Compositional requirements for food represented as being suitable for use as a sole source of nutrition

Division 4 - Labelling

Subdivision 1 – Outline of requirements

8 Labelling and related requirements

Subdivision 2 – General labelling requirements

- 9 Mandatory information
- 10 Mandatory statements
- 11 Mandatory declaration
- 12 Labelling of ingredients
- 13 Date marking of food
- 14 Lactose claims in relation to food for special medical purposes
- 15 Claims in relation to gluten content of food for special medical purposes
- 16 Legibility requirements

Subdivision 3 – Labelling requirements for inner packages

17 Labelling requirements for inner packages

#### **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
  - 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.

#### 2A Deemed compliance with Standard for certain periods

- (1) This clause applies to a food for special medical purposes that does not comply with this Standard.
- (2) If the food for special medical purposes is present in Australia or New Zealand on the date of commencement of this Standard, the food for special medical purposes is taken to comply with this Standard during the period that starts on that date of commencement and ends on 28 June 2014.
- (3) If the food for special medical purposes is imported into Australia or New Zealand on a date after the date of commencement of this Standard, the food for special medical purposes is taken to comply with this Standard during the period that starts immediately prior to importation and ends on 28 June 2014.
- (4) If the food for special medical purposes is produced in Australia or New Zealand on a date after the date of commencement of this Standard, the food for special medical purposes is taken to comply with this Standard during the period that starts on the date the food for special medical purposes was produced and ends on 28 June 2014.

#### 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;

#### To commence on 18 January 2016

- (b) Standards 1.3.2 and 1.5.1;
- (c) Standards 2.9.2, 2.9.3 and 2.9.4;
- 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) Subclause 6(3) of Standard 1.5.3 applies to a food for special medical purposes as if such food were subject to Standard 1.2.1.
- (3) Subclause 1(2) of Standard 1.1.1 does not apply in relation to a food for special medical purposes that did not comply with Standard 2.9.5 on the date that Standard 2.9.5 commenced.

#### 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
  - 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 subclauses 14(4) and 15(5) of this Standard, any other substance if a nutrition content claim as defined in Standard 1.2.7 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			

(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 in relation to the lactose 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 lactose free may be made if the food contains no detectable lactose.
- (3) 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 2 g of lactose per 100 g of the food.
- (4) If a claim in relation to the lactose content of a food for special medical purposes is made 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.

#### 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 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 <sub>6</sub>	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			
lodine	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			
Magnesiani	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			
	iviagnesium potassium ottrate			

# SCHEDULE 1 (continued) Permitted forms of particular substances

Column 1	Column 2			
Substances	Permitted Form			
Manganese	Manganese glycerophosphate			
Molybdenum	Ammonium molybdate			
Potassium	Potassium glycerophosphate			
	Potassium lactate			
	Potassium L-pidolate			
Selenium	Selenium enriched yeast			
	Sodium hydrogen selenite			
	Sodium selenate			
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			
Carnitine	L-carnitine			
Carnulle	L-carnitine hydrochloride			
	L-carnitine hydrochionde  L-carnitine L-tartrate			
Choline				
CHOINE	Choline Choline bitartrate			
	Choline bilartrate  Choline chloride			
	Choline bydrogen tartrate			
Inacital	Choline hydrogen tartrate			
Inositol	Inositol			

# SCHEDULE 1 (continued) Permitted forms of particular substances

Column 1	Column 2
Substances	Permitted Form
Nucleotides	Adenosine 5'-monophosphate
	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
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 <sup>1</sup>		430 µg retinol equivalents <sup>1</sup>		
Thiamin	0.15 mg	No maximum set		
Riboflavin	0.2 mg	No maximum set		
Niacin	2.2 mg niacin equivalents <sup>2</sup>	No maximum set		
Vitamin B <sub>6</sub>	0.2 mg	1.2 mg		
Folate	25 μg	No maximum set		
Vitamin B <sub>12</sub>	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 <sup>3</sup>		
Vitamin E	1 mg alpha-tocopherol equivalents <sup>4</sup>	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 <sup>3</sup>	420 mg or 600 mg <sup>3</sup>		
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		
lodine	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		

<sup>1, 2,</sup> and 4 These numbers refer to the corresponding numbers in the footnotes in Schedule 1 in Standard 1.1.1.

<sup>&</sup>lt;sup>3</sup> The higher amount applies only to products intended for children aged one to ten years.

#### **Amendment History**

The Amendment History provides information about each amendment to the Standard. The information includes commencement or cessation information for relevant amendments.

These amendments are made under section 92 of the *Food Standards Australia New Zealand Act* 1991 unless otherwise indicated. Amendments do not have a specific date for cessation unless indicated as such.

#### About this compilation

This is a compilation of Standard 2.9.5 as in force on **30 October 2014** (up to Amendment No. 150). It includes any commenced amendment affecting the compilation to that date.

Prepared by Food Standards Australia New Zealand on 30 October 2014.

#### Uncommenced amendments or provisions ceasing to have effect

To assist stakeholders, the effect of any uncommenced amendments or provisions which will cease to have effect, may be reflected in the Standard as shaded boxed text with the relevant commencement or cessation date. These amendments will be reflected in a compilation registered on the Federal Register of Legislative Instruments including or omitting those amendments and provided in the Amendment History once the date is passed.

The following abbreviations may be used in the table below:

ad = added or inserted am = amended exp = expired or ceased to have effect rep = repealed

rs = repealed and substituted

**Standard 2.9.5** was published in the Food Standards Gazette No. FSC 74 on 28 June 2012 as part of Amendment No. 132 (F2012L01347 - 27 June 2012) and has been amended as follows:

Clause affected	A'ment No.	FRLI registration Gazette	Commencement (Cessation)	How affected	Description of amendment
C'ment	139	F2012L01347 27 June 2012 as am by F2013L00253 21 Feb 2013 FSC81 21 Feb 2013	21 Feb 2013	am	Commencement date for the Standard brought forward from 28 June 2014 to 21 February 2013
Table of Provs	139	F2013L00247 21 Feb 2013 FSC81 21 Feb 2013	21 Feb 2013	am	Insert reference to new clause 2A.
2A	139	F2013L00247 21 Feb 2013 FSC81 21 Feb 2013	21 Feb 2013	ad	New clause to clarify the transitional arrangements implementation of the Standard.
3(1)(b)	138	F2013L00050 14 Jan 2013 FSC 80 18 Jan 2013	18 January 2016	am	Omitting reference to Standard 1.1A.2 as a consequential amendment relating to Standard 1.2.7.
3(2)	150	F2014L01427 28 Oct 2014 FSC92 30 Oct 2014	30 Oct 2014	am	Subclause to update cross-reference.

Clause affected	A'ment No.	FRLI registration Gazette	Commencement (Cessation)	How affected	Description of amendment
3(3)	139	F2013L00247 21 Feb 2013 FSC81 21 Feb 2013	21 Feb 2013	ad	New subclause to clarify the transitional arrangements implementation of the Standard.
9(e)(iv)	138	F2013L00050 14 Jan 2013 FSC 80 18 Jan 2013	21 Feb 2013	rs	Replacing paragraph as a consequential amendment relating to Standard 1.2.7 originally to have commenced on 28 June 2014.
14	138	F2013L00050 14 Jan 2013 FSC 80 18 Jan 2013	21 Feb 2013	rs	Replacing clause as a consequential amendment relating to Standard 1.2.7 originally to have commenced on 28 June 2014.
15(5)	138	F2013L00050 14 Jan 2013 FSC 80 18 Jan 2013	21 Feb 2013	rep	Editorial note as a consequential amendment relating to Standard 1.2.7 originally to have commenced on 28 June 2014.
Sch 1	139	F2013L00247 21 Feb 2013 FSC81 21 Feb 2013	21 Feb 2013	am	Entries for Amino acids, carnitine, Choline, Inositol and Nucleotides to correct a typographical error.