Draft New Zealand Food (Supplemented Food) Standard 2008

Pursuant to section 11C of the Food Act 1981, the Minister for Food Safety issues the following food standard.

1 Title

This standard is the New Zealand Food (Supplemented Food) Standard 2008.

2 Commencement

This standard comes into force on [date].

3 Purpose

The purpose of this standard is to regulate supplemented foods that were formerly regulated under the Dietary Supplements Regulations 1985.

4 Application

(1) On the coming into force of this Standard a person selling supplemented foods may elect to comply with ─

(a) Part 1; or

(b) Part 2.

(2) On and from 1 September 2010, a person selling supplemented foods must comply with Part 1.

(3) By way of explanation, clause 16 provides that Part 2 expires on 1 September 2010.

Part 1 Supplemented Food Requirements

5 Interpretation

(1) In this standard, unless the context otherwise requires,—

Act means the Food Act 1981

Code means the Australia New Zealand Food Standards Code.

(2) Words or expressions defined in the Act or the Code and used but not defined in this standard have the same meaning as in the Act or in the Code.

(3) References to adequate intake (AI) and recommended daily intake (RDI) mean the age-appropriate figures published by the National Health and Medical Research Council of Australia in 2005, "*Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes (2005)*". http://www.moh.govt.nz/moh.nsf/pagesmh/4678

(4) A reference to maximum quantity per one day serving in relation to supplemented food means the amount of that food which is to be consumed in one day in accordance with directions specified in the label.

6 Meaning of supplemented food

(1) A supplemented food is a product that is represented as a food —

(a) for consumption by the general population; and

(b) that has a substance or substances added to it or that has been modified in some way—

(i) to perform a physiological role beyond the provision of a simple nutritive requirement; and

(ii) in relation to which the Code does not otherwise apply.

(2) A product is not a supplemented food if—

(a) it is a dietary supplement (as defined in the Dietary Supplement Regulations 1985); or

(b) it is—

(i) a medicine (as defined in the Medicines Act 1981); or

(ii) a controlled drug or restricted substance (as defined in the Misuse of Drugs Act 1975).

7 Certain aspects of Code apply

The following standards in the Australia New Zealand Food Standards Code apply to supplemented foods manufactured, sold or prepared for sale in New Zealand and or imported into New Zealand:

Clauses 6, 7, and 8 Columns 1 and 2 of the Schedule of Standard 1.1.1 Preliminary provisions

Standard 1.1.2 Supplementary Definitions for Foods

Standard 1.2.1 Application of labelling and other information requirements (excluding any references to 1.2.2 and part 2)

Standard 1.2.3 Mandatory warning and advisory statements and declarations

Standard 1.2.4 Labelling of ingredients (excluding Clause 2 (b), clause 6, 1(a) and 3)

Standard 1.2.5 Date marking of packaged food

Standard 1.2.6 Directions for Use and Storage

Standard 1.2.8 Nutrition information requirements (excluding clause 3 (b), (o), (p) and (q))

Standard 1.2.9 Legibility requirements

Standard 1.2.10 Characterising ingredients and components of food (excluding clause 2, 4 (g), (i) and (j))

Standard 1.3.1 Food additives (excluding Schedule 1 13.1, 13.2, 13.3 14.2., 14.3 in Schedule 1 of that Standard)

Standard 1.3.3 Processing aids

Standard 1.3.4 Identity and purity

Standard 1.4.1 Contaminants and natural toxicants

Standard 1.4.3 Articles and materials in contact with food

Standard 1.4.4 Prohibited and Restricted plants and fungi

Standard 1.5.2	Food produced using gene technology
Standard 1.5.3	Irradiation of food
Standard 1.6.1	Microbiological limits for food
Standard 2.1.1	Cereals and cereal products
Standard 2.2.1	Meat and meat products
Standard 2.2.2	Egg and egg products
Standard 2.2.3	Fish and fish products
Standard 2.3.2	Jam
Standard 2.4.1	Edible oils
Standard 2.4.2	Edible oil spreads
Standard 2.5.1	Milk
Standard 2.5.2	Cream
Standard 2.5.3	Fermented milk products
Standard 2.5.4	Cheese
Standard 2.5.5	Butter
Standard 2.5.6	Ice cream
Standard 2.5.7	Dried milks, evaporated milks and condensed milks
Standard 2.6.1	Fruit juice and vegetable juice
Standard 2.6.2	Non-alcoholic beverages and brewed soft drinks
Standard 2.8.1	Sugars
Standard 2.8.2	Honey
Standard 2.10.1	Vinegar and related products
Standard 2.10.2	Salt and salt products

8 Identification requirements

(1) The label on a package of supplemented food must include the words “supplemented food”.

(2) The words “supplemented food” must be placed in a prominent position in any advertising material.

(3) The label on a package of supplemented food must include its lot identification, unless the supplemented food is in small packages, and the bulk packages and the bulk container in which the food is stored or displayed for sale includes its lot identification.

(4) The label on a package of supplemented food must include the name and business address in New Zealand of the supplier of the supplemented food.

9 Restrictions on advertising and labelling supplemented foods

(1) Subclauses (2) and (3) apply to any—

(a) advertisement for a supplemented food; and

(b) container or package in which a supplemented food is sold; and

(c) label on a package or container in which a supplemented food is sold.

(2) An item listed in subclause (1) must not claim or make a statement, express or implied relating to any of the following matters:

(a) that the supplemented food treats or prevents disease:

(b) that the supplemented food diagnoses disease or ascertains the existence, degree, or extent of a physiological condition:

(c) that the supplemented food alters the shape, structure, size, or weight of the human body; or has slimming or intrinsic weight reducing properties:

(d) that the supplemented food prevents the normal operation of a physiological function (whether permanently, temporarily, or by way of terminating, reducing, postponing, increasing, or accelerating the operation of that function or in any other way).

(3) An item listed in subclause 1 must not—

(a) include on its label the word ‘health” or any word or words of similar import as a part of or in conjunction with the name of the food; and

(b) have a label that contains any word, statement, claim, express or implied or design that directly or by implication could be interpreted as advice of a medical nature from any person.

10 Restrictions on content claims of vitamins and minerals

(1) A claim must not be made in relation to the presence of a vitamin or mineral in a supplemented food unless–

(a) the vitamin or mineral is listed in column 1 of the Schedule to Standard 1.1.1 of the Code; and

(b) a reference quantity of the food contains at least 10% of the RDI or AI for that vitamin or mineral.

(2) A claim must not be made in relation to a supplemented food being a good source of a vitamin or mineral unless–

(a) the vitamin or mineral is listed in column 1 of the Schedule to Standard 1.1.1 of the Code; and

(b) a reference quantity of the food contains at least 25% of the RDI or AI for that vitamin or mineral.

11 Restriction on including intoxicating substance

A supplemented food may not contain any substance that is intended to have an intoxicating effect on any person who consumes it.

12 Substances that may be added to supplemented foods subject to restrictions

The substances listed in column 1 of Table 1 (with the common names in column 2) are only able to be added to supplemented foods if there is compliance with the restrictions specified in column 3.

Table 1 Substances subject to restrictions

Substance Column 1	Common name Column 2	Restrictions Column 3
Species name Hypericum perforatum	St John's Wort	Only to be used in herbal infusions The package must contain the following Mandatory Warning Statement: "Consult your doctor if you take prescription medicines before using this product. Do not take if pregnant."
Chemical Glucosamine		If sourced from seafood, the packaging must contain the following statement: "derived from seafood".
Caffeine (including guarana)		If the product contains greater than 320mg/l of caffeine. The label must include advisory statements to the effect that the food contains caffeine and is not recommended for children, pregnant or lactating women and individuals sensitive to caffeine.

13 Substances prohibited in supplemented foods

The substances listed column 1 of Table 2 (with the common name in column 2) must not be added to supplemented foods.

Table 2 Prohibited substances

Substance Column 1	Common name Column 2
Species name Actaea/Cimicifuga racemosa	Black Cohosh

14 Restrictions on the addition of vitamins and minerals to supplemented food products (other than those produced for children aged 0 to 8 years)

(1) The vitamins and minerals listed in column 1 of Table 3 may be added to a supplemented food (other than a supplemented food produced for children aged 0 to 8 years) up to the maximum quantity per one day serving specified in column 2 of Table 3.

Table 3 Maximum Supplemented Food Levels for Vitamins and Minerals per day for Adults

Nutrients Column 1	**Maximum Quantity Per One Day Serving** Column 2
Vitamins	
Choline	1750mg
Folic acid	500 mcg
Nicotinic Acid	17.5 mg
Nicotinamide	450 mcg
Retinol	1500 mcg
Pyridoxine	25 mg
Vitamin C	500 mg
Vitamin D	40 mcg
Vitamin E (as alpha-tocopherol equivalents)	150 mg
Minerals	
Calcium	1250 mg
Copper	5 mg
Fluoride	5 mg
Iodine	550 mcg
Iron	22.5 mg
Magnesium	175 mg
Molybdenum	1000 mcg
Phosphorous	2000 mg
Selenium	200 mcg
Sodium	1150 mg
Zinc	20 mg

(2) The vitamins and minerals listed in column 1 of table 4 may only be added to supplemented foods if the package contains the warning statement set out in column 3.

Table 4 Vitamins and Minerals that require warning statements

Nutrients Column 1	**Warning Statement** Column 2
Vitamin K	Must include a warning statement for patients prescribed warfarin medication

15 Restrictions on the addition of vitamins and minerals to supplemented food for children aged 0 to 8 years

(1) The vitamins and minerals listed in column 1 of Table 5 may only be added to a supplemented food produced for a child aged any where between 0 and 8 years up to the maximum quantity per one day serving specified in column 2 of Table 5.

Table 5 Maximum Supplemented Food Levels for Vitamins and Minerals per day for Children aged 0 to 8 years

Nutrients Column 1	**Maximum Quantity Per One Day Serving** Column 2
Vitamins	
Choline	500 mg
Folic acid	200 mcg
Nicotinic Acid	7.5 mg
Nicotinamide	125 mcg
Retinol	450 mcg
Pyridoxine	10 mg
Vitamin C	500 mg
Vitamin D	40 mcg
Vitamin E (as alpha-tocopherol equivalents)	50 mg
Minerals	
Calcium	1250 mg

Copper	1.5 mg
Fluoride	1.1 mg
Iodine	150 mcg
Iron	20 mg
Magnesium	55 mg
Molybdenum	300 mcg
Phosphorous	1500 mg
Selenium	75 mcg
Sodium	700 mg
Zinc	6 mg

(2) Supplemented food products produced specifically for children aged anywhere between 0 and 8 years must be labelled “Produced for children”.

16 Expiry of Part

This Part expires on 1 September 2010.

17 Interpretation

(1) In this Part, unless the context otherwise requires,-

batch means a quantity of supplemented food produced under essentially the same conditions during a particular period, and usually from a particular "line" or other identifiable processing unit

common name, in relation to a supplemented food, means the name by which the supplemented food is generally known

container means any box, packet, or other receptacle in which 1 or more packages of supplemented food are, or are to be, enclosed

supplemented food has the same meaning as in Part 1

incidental constituent means any extraneous substance, toxic substance, or pesticide that is contained or present in or on any food; but does not include any preservative, antioxidant, colouring substance, artificial sweetener, flavouring substance, food conditioner, anticaking agent, gaseous packing agent, propellant, or vitamin, or any mineral

ingredient means any substance including a food additive (other than an incidental constituent), that is—

(a) used in the manufacture or preparation of a supplemented food; and

(b) present, whether in a modified form or not, in the final product

principal display panel means the part of a label that is most likely to be displayed, presented, shown, or examined, under ordinary or customary conditions of display for retail sale; and, if such likelihood is equal in respect of 2 or more panels, means every such panel

printed includes written, typewritten, engraved, lithographed, or otherwise traced or copied.

(2) In this Part, the symbols specified in the first column of the table have the meanings specified in relation to those symbols in the second column of the table (as follows):

TABLE TO SUBCLAUSE 2	
Symbol	**Meaning**
G	grams
Mcg	micrograms
Mg	milligrams
Mm	millimetres
Ppm	parts per million

(3) In this Part, unless the context otherwise requires, all references to proportions (whether as percentages, parts per million, or otherwise) are references to proportions by weight in a supplemented food as sold.

(4) Nothing in this Part prohibits the use of any symbol the style of which conforms with a specimen in the table to subclause 2 of this Part, or with the conventional usage of metric measurements.

18 Maximum daily doses

(1) A supplemented food described as or containing minerals or vitamins specified in the first column of the following table must be manufactured so that each daily dose (for an adult) does not contain more than the maximum specified in the second column of the following table:

Vitamin or mineral Column 1	**Maximum Daily Dose** Column 2
Copper	5 mg
Iron	24 mg
Selenium	150 mcg
Zinc	15 mg
Vitamins	
Vitamin A or retinol	3000 mcg
Niacin (and salts) or nictonic acid (and salts)	100 mg
Vitamin B12 or cyanocobalamin or hydroxocobalamin	50 mcg
Vitamin D	25 mcg
Folic Acid	300 mcg

(2) A supplemented food described as or containing any mineral, other than a mineral specified in subclause (1), must be manufactured so that each daily dose (for an adult) does not contain more than the maximum specified in the current edition of Recommended Dietary Allowances, published by the Food and Nutrition Board of the National Academy of Science and National Research Council, Washington DC, USA.

19 Supplemented food not to be sold unless properly labelled

No person may sell any package or container containing any supplemented food, or any supplemented food contained in a package or container,—

(a) does not bear a label containing all the particulars required by this Part; or

(b) bears a label containing anything that is prohibited by this Part; or

(c) bears a label containing any particulars that are not in the position, manner, and style required by this Part.

20 General requirements for labelling

(1) A package and container containing a supplemented food must, unless otherwise provided in This Part, bear a label that includes the following:

(a) the common name of the supplemented food, or a description (other than the brand name of the supplemented food) sufficient to indicate the true nature of the supplemented food, or a description of the supplemented food including the common names of its principal ingredients; and

(b) a statement of the net weight or volume or number of the contents of the package or container, whichever measure is appropriate for retail sale of the supplemented food; and

(c) the trading name and business address of the manufacturer or seller or packer of the supplemented food, or of the owner of the rights of manufacture, or of the principal or the agent of any of them; and

(d) consumer information panel that complies with clause 15:

(e) the words “DIETARY SUPPLEMENT”:

(f) a batch number:

(g) a date mark, being an expression in one of the following forms (that is a date no later than 5 years after the date of manufacture):

(i) use by (followed by a date); or

(ii) not to be consumed after (followed by a date); or

(iii) words of similar meaning (followed by a date);—

(h) A statement of the recommended daily dosage (for an adult) both as to quantity and frequency, which must not exceed the maximum daily dose permitted by clause 9, and, if the supplemented food is suitable for children, the recommended daily dose for children:

(i) A warning in any case where a danger exists if an overdose is taken:

(j) the method of preparation before use (where necessary).

(2) Despite subclause (1)(f) and (g), no container containing a supplemented food need be labelled with the batch number or with a date mark.

(3) Despite subclause (1), if supplemented foods are packed in blister or strip packaging, the packaging must be labelled with—

(a) the common name; and

(b) a batch number.

(4) For the purposes of subclause (1)(c)─

(a) postal address, not being a telegraphic or code address or an address at a Post Office, must be given:

(b) the name and address of a person who is not ordinarily resident in New Zealand must not be sufficient unless the supplemented foods is wholly manufactured and packed outside New Zealand:

(c) the case where the trading name is of a body corporate (whether registered inside or outside New Zealand), either the name of the town in which the body corporate has its registered office or the full postal address of the premises where the supplemented foods is actually manufactured or packed by the body corporate must be given as the address.

(5) Where a package or container of a supplemented food is enclosed or wrapped in a transparent covering and the particulars with which that package or container is required to be labelled are clearly visible through that covering, that covering must be exempt from the labelling requirements under this Part

(6) No person who has in that person's possession any package or container of a supplemented food intended for sale by retail may—

(a) remove any label required by this Part to be on the package or container; or

(b) alter, erase, obliterate, or obscure any word or statement borne on such a label in accordance with any of the requirements of this Part.

21 Form and manner of labelling

(1) A word or statement that is required by this Part to be borne on a label must—

(a) be conspicuously printed and, for each statement separately required, be in uniform colour contrasting strongly with a uniform background; and

(b) be clearly, legibly, and durably marked either on the material of the package or container or on material firmly and securely attached to the package or container; and

(c) be presented with continuity.

(2) The lettering of every word or statement required by this Part must be clear, distinct, and legible with no decoration, embellishment, or distortion that could interfere with the legibility of the words.

22 Size of letters

(1) The lettering of every word or statement required by this Part to appear on labels must be—

(a) capital letters; or

(b) lower case letters; or

(c) lower case letters with an initial capital letter.

(2) In every case to which subclause (1) (a) or (b) applies, the height of the lettering must be uniform in every word or statement that is separately required.

(3) In every case to which subclause (1)(c) applies, the height of the lower case lettering must be uniform in every word or statement that is separately required.

(4) Except as otherwise provided in this Part, the lettering of any word or statement required by this Part to appear on labels must be not less than 1.5mm in height, except where the package or container to be labelled is so small as to prevent the use of letters of that height, in which case letters of not less than 0.75mm in height may be used.

(5) The height of the lettering for the common name or description that is required by this Part to appear in the principal display panel of a label must be not less than one-third of the height of the largest lettering appearing in that panel, and—

(a) Not less than one-twentieth of the height of the label, in the case of a label that is no longer than twice the width of the label; and

(b) Not less than one-thirtieth of the height of the label, in any other case.

(6) For the purposes of subclause (5), the height of a label is the distance between the top and bottom of all printed or pictorial information on the label.

23 Principal display panel

(1) The particulars that are required by clause 23 to appear on a label must appear in the principal display panel.

(2) Every word or statement that is required by this Part to appear in the principal display panel of a label must be in lines that are generally parallel to the base on which the package or container rests as it is designed to be displayed.

(3) In the case of a cylindrical package or container, the width of the principal display panel on the cylindrical surface must not exceed one-third of the circumference of the package or container.

24 Consumer information panel

(1) The following information, when required by this Part to be on the label, must be grouped together in one portion of the label (that portion being called the consumer information panel):

(a) the statement of ingredients, which must show—

(i) the quantities or proportions of the claimed active ingredients in the package or container or in each dosage unit, or, where the dietary supplement is divided into a number of units, the quantity or proportion of the claimed active ingredients in each unit; and

(ii) the inactive ingredients in the package or container, which must be described either by their specific names or by their class names, being any of the following permitted class names:

Antioxidants:

Artificial sweeteners:

Colouring or colour:

Flavouring or flavour:

Minerals:

Preservatives:

Vitamins:

(b) the storage instructions (where appropriate).

(2) The consumer information panel may be any part of the label, but must—

(a) be conspicuously placed in relation to other information included on the label; and

(b) be clearly differentiated from all other promotional material or illustrations.

25 Misleading statements

(1) No printed, pictorial, or other descriptive matter appearing on or attached to or supplied or displayed with any dietary supplement must include any comment on, reference to, or explanation of any word, statement, or label required by this Part to be borne on any supplemented food if that comment, reference, or explanation either directly or by implication contradicts, qualifies, or modifies that word or statement or the contents of that label.

(2) No printed, pictorial, or other descriptive matter supplied or displayed with any supplemented food must include any false or misleading statement, word, brand, picture, or mark purporting to indicate the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects, or proportion of the dietary supplement or of any ingredients of the supplemented food.

26 Therapeutic claims

Except as permitted by the Medicines Act 1981 and any regulations made under that Act, no supplemented food or package or container containing a supplemented food may be advertised or labelled with a statement relating to any of the following matters:

(a) treating or preventing disease:

(b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition:

(c) altering the shape, structure, size, or weight of the human body:

(d) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way.

Subpart 2 Specific requirements

27 Preservatives

(1) In this clause preservative means any substance that, when added to a dietary supplement, has the property of arresting or impeding fermentation, putrefaction, or decomposition.

(2) Supplemented foods may contain any of the following preservatives and no others:

Benzoic acid or sodium benzoate:

Parahydroxybenzoic acid and its esters:

Sorbic acid, or its sodium, calcium, or potassium salts:

Sulphur dioxide, or sulphites calculated as sulphur dioxide.

28 Antioxidants

(1) In this clause, antioxidant means any substance that, when added to a supplemented food, has the property of arresting or retarding oxidative rancidity.

(2) Supplemented foods may contain any of the following antioxidants and no others:

(a) Propyl gallate, dodecyl gallate, octyl gallate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), and tertiary butylhydroquinone (TBHQ), where the proportion of those antioxidants, singly or in combination, does not exceed 100ppm:

(b) Ascorbyl palmitate, and ascorbyl stearate, where the proportion of those antioxidants, singly or in combination, does not exceed 500ppm:

(c) Natural tocopherols, synthetic tocopherols, citric acid, and sodium citrate:

(d) Isopropyl citrate mixture, monoglyceride citrate, and phosphoric acid, where the proportion of those antioxidants, whether singly or in combination, does not exceed 100ppm.

29 Colouring substances

(1) In this clause colouring substance means any substance that, when added or applied to a supplemented food, is capable of imparting colour to that supplemented food.

(2) Supplemented foods may contain any of the colouring substances (and, where appropriate, their aluminium lakes) specified in the table to this subclause and no others.

TABLE TO SUBCLAUSE 2		
Common Name	**Index Name**	**Index Number**
Allura Red AC	CI Food Red 17	16035
Aluminium		77000
Amaranth	CI Food Red 9	16185
Annatto extracts (bixin, norbixin)	CI Natural Orange 4	75120
Anthocyanins Beet red (betanin) B-carotene	CI Food Orange 5	40800
B-apo-8'-carotenol	CI Food Orange 6	40820
B-apo-8'-carotenoic acid, and its ethyl and methyl esters	CI Food Black 6 CI Food Orange 7	40825
Brilliant Black PN	CI Food Black 1	28440
Brilliant Blue FCF	CI Food Blue 2	42090
Brown HT	CI Food Brown 3	20285
Canthaxanthin	CI Food Orange 8	40850
Caramel		14720
Carmoisine (azorubine)	CI Food Red 3	
Chlorophyll	CI Natural Green 3	75810
Chlorophyll copper complex		75470
Chlorophyllin copper complex, potassium and sodium salts		
Cochineal (carminic acid)	CI Natural Red 4	
Erythrosine	CI Food Red 14	45430
Fast Green FCF	CI Food Green 3	42053
Gold		77480
Grape skin extracts		44090
Green S	CI Food Green 4	
Indigotine (indigo carmine)	CI Food Blue 1	73015
	CI Pigment Red 101 & 102	77491
Iron oxides and hydrated iron oxides	CI Pigment Yellow 42 & 43	77492

	CI Pigment Black 11	77499
Paprika (paprika oleoresin) (capsanthin and capsorubin)		16255
Ponceau 4R	CI Food Red 7	
Roboflavin (lactoflavin)		75100
Riboflavin-5-phosphate		
Saffron (crocin, crocetin)	CI Natural Yellow 6 & 19	
Silver		77820
Sunset Yellow FCF	CI Food Yellow 3	15985
Tartrazine	CI Food Yellow 4	19140
Titanium dioxide		77891
Turmeric (curcumin)	CI Natural Yellow 3	75300
Xanthophylls	CI Natural Yellow 27	75135

NOTE: The index numbers specified in the third column of this table are the numbers allotted in the current edition of the Colour Index published jointly by the Society of Dyers and Colourists of the United Kingdom and the Association of Textile Chemists and Colorists of the United States of America.

30 Artificial sweeteners

(1) In this clause artificial sweetener means any substance that when added to a supplemented food, is capable of imparting sweetness to that supplemented food, and that is not a saccharide, polyhydric alcohol, or honey.

(2) Supplemented foods may contain any of the following artificial sweeteners and no others:

Aspartame:

Saccharin and its sodium, and calcium and ammonium compounds:

Sodium cyclamate and calcium cyclamate.

31 Flavouring substances

(1) In this clause flavouring substance means any wholesome substance that, when added or applied to a dietary supplement, is capable of imparting flavours to, or enhancing flavours in, that supplemented food.

(2) Supplemented foods may contain any flavouring substance, except the following:

Cade oil:

Coumarin:

Nitrobenzene:

Pyroligneous acid:

Safrole and isosafrole:

Sassafras oil.

32 Vitamins

(1) The supplemented food specified in the first column of the table to this subclause, or any compound of those supplemented food, and no others, may be described as vitamins, and the quantity of vitamins in supplemented foods must be calculated in accordance with the second column of that table.

TABLE TO SUBCLAUSE (1)	
Dietary Supplement described as vitamins or containing vitamins	**Calculated as**
Vitamin A or retinol	retinol in mcg
Vitamin B1, or thiamine	thiamine in mg
Vitamin B2 or riboflavin	riboflavine in mg
Niacin or nocotinic acid	niacin equivalents in mg
Pantothenic acid	pantothenic acid in mg
Vitamin B6, or pyridoxine	pyridoxine in mg
Vitamin B12, or cyanocobalamin, or hydroxycobalamin	vitamin B12 in mcg

Vitamin C or ascorbic acid	ascorbic acid in mg
Vitamin D2 or calciferol	calciferol in mcg
Vitamin D3 or cholecalciferol	cholecalciferol in mcg
Vitamin E	Vitamin E in mg
Biotin	biotin in mcg
Vitamin K	vitamin K in mcg
Vitamin K1, or phytomenadione	vitamin K1 in mcg
Vitamin K3, or menaphthone	vitamin K3 in mcg
Folic acid	folic acid in mcg

(2) If the quantity of vitamins in a supplemented food is declared on a label, it must be stated to an accuracy of not greater than 3 significant figures.

(3) There may be marked on any package or container containing a supplemented food, described as or containing a vitamin, a statement indicating—

(a) the presence of vitamins; and

(b) the quantity, calculated in accordance with the table to subclause (1), of that vitamin in that package or container or in each dosage unit, or, where the supplemented food is divided into a number of units, the quantity of that vitamin in each unit.

33 Minerals

(1) The following substances may be described as minerals in supplemented foods:

Calcium:

Chlorine:

Chromium:

Copper:

Fluorine:

Iodine:

Iron:

Magnesium:

Manganese:

Molybdenum:

Phosphorus:

Potassium:

Selenium:

Sodium:

Zinc.

(2) If the quantity of minerals in a supplemented food is declared on a label, it must be stated in milligrams or micrograms to an accuracy of not greater than 3 significant figures.

(3) There may be marked on any package or container containing a supplemented food as or containing a mineral, a statement indicating—

(a) The presence of minerals; and

(b) The quantity of that mineral in that package or container or in each dosage unit, or, where the dietary supplement is divided into a number of units the quantity of that mineral in each unit.

34 Enzymes

The following enzymes may be added to supplemented foods:

Amylase and protease derived from Aspergillus flavus oryzae or Aspergillus niger:

Bromelin:

Ficin:

Invertase:

Papain:

Pectinase:

Pepsin:

Rennet and protein—coagulating enzymes:

Lactase:

Lipase.

35 Appendix 2: Legislative Requirements

The Food Act 1981 sets specific requirements that must be met before making a Food Standard, including matters that the Minister must take into account and also be satisfied about. These are set out in Section 11E 'Preconditions for issuing food standard'.

Food Act 1981, Section 11E—Preconditions for issuing food standard

(1) In issuing any food standard, the Minister shall take into account the following:

a. The need to protect public health

b. The desirability of avoiding unnecessary restrictions on trade

c. The desirability of maintaining consistency between New Zealand's food standards and those applying internationally

d. New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australian-New Zealand Joint Food Standards Agreement

e. Such other matters as the Minister considers appropriate.

(2) The Minister shall not issue any food standard unless the Minister is satisfied that appropriate consultation has been carried out with respect to the food standard, including (without limitation)—

a. Adequate and appropriate notice of the intention to issue the food standard; and

b. A reasonable opportunity for interested persons to make submissions; and

c. Adequate and appropriate consideration of any such submissions.

The proposed Supplemented Food Standard meets the preconditions of section **11E(1)** as described below:

a. The need to protect public health

The main objective of the proposal is to protect public health and safety by ensuring that supplemented food is subject to the same standards as most other foods available in New Zealand

b. The desirability of avoiding unnecessary restrictions on trade

The objectives of the proposed standard include supporting economic growth and maintaining an existing right for New Zealand consumers, manufacturers, importers and exporters. In addition, aligning the supplemented food with the requirements of the Australia New Zealand Food Standards Code (the Code) to the maximum extent possible will reduce the impact on trans Tasman trade resulting from separate standards for these products.

c. The desirability of maintaining consistency between New Zealand's food standards and those applying internationally.

There is no standard approach to the regulation of these products internationally. However, where applicable for substances added to supplemented food, Codex standards have been referenced.

d. New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australian-New Zealand Joint Food Standards Agreement.

The Dietary Supplements Regulations were in force at the time the Food Treaty was signed. It was always intended that standards under the Food Code would supersede the Dietary Supplements Regulations. Although the matter has been subject to considerable discussion, suitable standards have yet to be developed. In the absence of suitable joint standards the Supplemented Food Standard provides maximum alignment with the objective of eventual

e. Such other matters as the Minister considers appropriate.

It is acknowledged that there is a significant industry that has operated under the Dietary Supplements Regulations. Maintaining this existing right is a consideration

The proposals to issue a Supplemented Food Standard meet the requirements for consultation in **11E(2)** as described below:

a. Adequate and appropriate notice of the intention to issue the food standard.

Changes to the regulation of dietary supplements have been under discussion since 2004. Following the analysis of submissions to the 2007 consultation process, changes were agreed by Government and conveyed to industry via letter, website and seminars

b. A reasonable opportunity for interested persons to make submissions.

There have been two rounds of consultation relating to the general proposal (2004 and 2007). This round of consultation provides an opportunity to consider the technical detail of the proposal.

c. Adequate and appropriate consideration of any such submissions.

All submissions will be considered in the context of earlier policy decisions and with regard to the level of regulatory compliance costs.