1985/208

THE DIETARY SUPPLEMENTS REGULATIONS 1985

DAVID BEATTIE, Governor-General

ORDER IN COUNCIL

At the Government Buildings at Wellington this 19th day of August 1985

Present:

THE HON. G. W. R. PALMER PRESIDING IN COUNCIL

PURSUANT to section 42 of the Food Act 1981, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, hereby makes the following regulations.

ANALYSIS

REGULATIONS

1. Title and commencement—(1) These regulations may be cited as the Dietary Supplements Regulations 1985.

(2) This regulation, regulation 2, and regulations 4 to 11 of these regulations shall come into force on the 1st day of September 1987.

(3) Except as provided in subclause (2) of this regulation, these regulations shall come into force on the 1st day of September 1985.

2. Interpretation—(1) In these regulations, unless the context otherwise requires,—

"Batch" means a quantity of dietary supplement 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 dietary supplement, means the name by which the dietary supplement is generally known, being a noun defined in a dictionary of the English language of authority and repute in New Zealand to mean that kind of dietary supplement; and also means any expression containing such a noun:

"Container" means any box, packet, or other receptacle in which 1 or more packages of dietary supplements are, or are to be, enclosed:

"Dietary supplement" means any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets, which are intended to supplement the intake of those substances normally derived from food:

"Foodstuff" means—

(a) Any food for which a standard is prescribed in any of the provisions of Part II of the Food Regulations 1984, except regulations 47, 51, 52, 54, 55, 73, 76, 196 to 200, and 202 to 204, whether or not the food is permitted by the relevant standard to contain a food additive:

(b) Any other food that does not contain a food additive other than an incidental constituent:

"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 dietary supplement; 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 these regulations, the symbols specified in the first column of the table to this subclause shall have the meanings specified in relation to those symbols in the second column of the table.

TABLE TO SUBCLAUSE (2)

Symbol	Meaning
g	grams
mcg	micrograms
mg	milligrams
mm	millimetres
ppm	parts per million

(3) In these regulations, unless the context otherwise requires, all references to proportions (whether as percentages, parts per million, or otherwise) shall be references to proportions by weight in a dietary supplement as sold.

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

PART I

GENERAL REQUIREMENTS

3. Maximum daily doses—(1) Every dietary supplement described as or containing minerals or vitamins specified in the first column of the table to this subclause shall be so manufactured that each daily dose (for an adult) does not contain more than the maximum specified in the second column of the table.

TABLE TO SUBCLAUSE (1)

Dietary Supplement	Maximum Daily Dose (For Adult)
Minerals:	
Copper	5 mg
Iron	24 mg
Selenium	150 mcg
Zinc	15 mg
Vitamins:	
Vitamin A or retinol	3000 mcg
Niacin (and salts) or nicotinic acid (and salts)	100 mg
Vitamin B_{12} or cyanocobalamin or hydroxocobalamin	50 mcg
Vitamin D	25 mcg
Folic acid	300 mcg

(2) Every dietary supplement described as or containing any mineral, other than a mineral specified in regulation 19 (1) of these regulations, shall be so manufactured 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 D.C., U.S.A.

4. Dietary supplements not to be sold unless properly labelled—No person shall sell any package or container containing any dietary supplement, or any dietary supplement contained in a package or container, if the package or container—

(a) Does not bear a label containing all the particulars required by these regulations to be contained on a label relating to such package or container; or

(b) Bears a label containing anything that is prohibited by these regulations from appearing on a label relating to such package or container; or

(c) Bears a label containing any particulars that are not in the position, manner, and style required by these regulations in respect of a label relating to such package or container.

5. General requirements for labelling of dietary supplements—(1) Every package and container containing a dietary supplement shall, unless otherwise provided in these regulations, bear a label that includes the following:

(a) The common name of the dietary supplement, or a description (other than the brand name of the dietary supplement) sufficient to indicate the true nature of the dietary supplement, or a description of the dietary supplement including the common names of its principal ingredients:

(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 dietary supplement concerned:

(c) The trading name and business address of the manufacturer or seller or packer of the dietary supplement, or of the owner of the rights of manufacture, or of the principal or the agent of any of them:

(d) A consumer information panel that complies with regulation 9 of these regulations:

(e) The words "DIETARY SUPPLEMENT":

(f) A batch number:

(g) A date mark, being an expression in one of the following forms:

(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);*—

the relevant date in any case being no later than 5 years after the date of manufacture:

(h) A statement of the recommended daily dosage (for an adult) both as to quantity and frequency, which shall not exceed the maximum daily dose permitted by regulation 3 of these regulations, and, if the dietary supplement 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) Notwithstanding paragraphs (f) and (g) of subclause (1) of this regulation, no container containing a dietary supplement need be labelled with the batch number or with a date mark.

(3) Notwithstanding subclause (1) of this regulation, where dietary supplements are packed in blister or strip packaging, the packaging shall be labelled with—

(a) The common name; and

(b) A batch number.

(4) For the purposes of subclause (1) (c) of this regulation,—

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

(b) The name and address of a person who is not ordinarily resident in New Zealand shall not be sufficient unless the dietary supplement is wholly manufactured and packed outside New Zealand:

(c) In 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 dietary supplement is actually manufactured or packed by the body corporate shall be given as the address.

(5) Where a package or container of a dietary supplement 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 shall be exempt from the labelling requirements under these regulations.

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

(a) Remove any label required by these regulations 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 these regulations.

6. Form and manner of labelling—(1) Every word or statement that is required by these regulations to be borne on a label shall—

(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 these regulations shall be clear, distinct, and legible with no decoration, embellishment, or distortion that could interfere with the legibility of the words.

7. Size of letters—(1) The lettering of every word or statement required by these regulations to appear on labels shall be—

(a) All capital letters; or

(b) All lower case letters; or

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

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

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

(4) Except as otherwise provided in these regulations, the lettering of any word or statement required by these regulations to appear on labels shall be not less than 1.5 mm 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 0.75 mm in height may be used.

(5) The height of the lettering for the common name or description that is required by these regulations to appear in the principal display panel of a label shall 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) of this regulation, the height of a label is the distance between the top and bottom of all printed or pictorial information on the label.

8. Principal display panel—(1) The particulars that are required by paragraph (a) and paragraph (b) and paragraph (e) of regulation 5 (1) of these regulations to appear on a label shall appear in the principal display panel.

(2) Every word or statement that is required by these regulations to appear in the principal display panel of a label shall 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 shall not exceed one-third of the circumference of the package or container.

9. Consumer information panel—(1) The following information, when required by these regulations to be on the label, shall be grouped together in one portion of the label (that portion being called the consumer information panel):

(a) The statement of ingredients, which shall 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 shall 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:
Encapsulating aids:
Flavouring or flavour:
Minerals:
Preservatives:
Tabletting aids:
Vitamins:

(b) The storage instructions (where appropriate).

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

(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.

10. Misleading statements—(1) No printed, pictorial, or other descriptive matter appearing on or attached to or supplied or displayed with any dietary supplement shall include any comment on, reference to, or explanation of any word, statement, or label required by these regulations to be borne on any dietary supplement 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 dietary supplement shall 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 dietary supplement.

11. Therapeutic claims—Except as permitted by the Medicines Act 1981 and any regulations made under that Act, no dietary supplement or package or container containing a dietary supplement shall 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.

PART II

SPECIFIC REQUIREMENTS

12. Tabletting aids—(1) In these regulations "tabletting aid" means a food grade substance that is added to a dietary supplement to constitute the form in which that supplement is sold; and includes an encapsulating aid.

(2) The following tabletting aids or encapsulating aids, and any other food conditioners specified in the Food Regulations 1984*, may be added to dietary supplements:

Alginic acid and its derivatives:
Beeswax:
Bone meal (sterilised); calcium phosphate:
Carbohydrate sweeteners:
Carnauba wax:
Cellulose and its derivatives:
Coating pigments:
Enteric coatings:
Gelatin:
Gelatin capsule shells:

Lactose:
Lecithin:
Light mineral oils:
Monoglycerides, diglycerides, and triglycerides from edible oils and fats:
Montan ester wax:
Pectins:
Polyethylene glycols:
Polyvinylpyrrolidone and its derivatives:
Shellac:
Silicic acid and its salts:
Starch:
Starches (modified):
Stearic acid and its salts:
Talc (sterilised):
Vegetable gums:
Vegetable oils, and hydrogenated vegetable oils:
Xanthan gum:
Zein corn protein.

13. Preservatives—(1) In these regulations "preservative" means any substance that, when added to a dietary supplement, has the property of arresting or impeding fermentation, putrefaction, or decomposition.

(2) Dietary supplements 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.

14. Antioxidants—(1) In these regulations "antioxidant" means any substance that, when added to a dietary supplement, has the property of arresting or retarding oxidative rancidity.

(2) Dietary supplements 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 100 ppm:

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

(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 100 ppm.

15. Colouring substances—(1) In these regulations "colouring substance" means any substance that, when added or applied to a dietary supplement, is capable of imparting colour to that dietary supplement.

(2) Dietary supplements 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		40800
Beet red (betanin)		
β-carotene	CI Food Orange 5	
β-apo-8'-carotenol	CI Food Orange 6	40820
β-apo-8'-carotenoic acid, and its ethyl and methyl esters	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
Iron oxides and hydrated iron oxides	CI Pigment Red 101 & 102	77491
	CI Pigment Yellow 42 & 43	77492
	CI Pigment Black 11	77499
Paprika (paprika oleoresin) (capsanthin and capsorubin)		16255
Ponceau 4R	CI Food Red 7	
Riboflavin (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.

16. Artificial sweeteners—(1) In these regulations "artificial sweetener" means any substance that when added to a dietary supplement, is capable of imparting sweetness to that dietary supplement, and that is not a saccharide, polyhydric alcohol, or honey.

(2) Dietary supplements 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.

17. Flavouring substances—(1) In these regulations "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 dietary supplement.

(2) Dietary supplements may contain any flavouring substance, except the following:

Cade oil:
Coumarin:
Nitrobenzene:
Pyroligneous acid:
Safrole and isosafrole:
Sassafras oil.

18. Vitamins—(1) The dietary supplements specified in the first column of the table to this subclause, or any compound of those supplements, and no others, may be described as vitamins, and the quantity of vitamins in those dietary supplements shall 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 B_1 or thiamine	thiamine in mg
Vitamin B_2 or riboflavin	riboflavine in mg
Niacin or nicotinic acid	niacin equivalents in mg
Pantothenic acid	pantothenic acid in mg
Vitamin B_6 or pyridoxine	pyridoxine in mg
Vitamin B_{12} or cyanocobalamin, or hydroxycobalamin	vitamin B_{12} in mcg
Vitamin C or ascorbic acid	ascorbic acid in mg
Vitamin D_2 or calciferol	calciferol in mcg
Vitamin D_3 or cholecalciferol	cholecalciferol in mcg
Vitamin E	vitamin E in mg
Biotin	biotin in mcg
Vitamin K	vitamin K in mcg
Vitamin K_1 or phytomenadione	vitamin K_1 in mcg
Vitamin K_3 or menaphthone	vitamin K_3 in mcg
Folic acid	folic acid in mcg

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

(3) There may be marked on any package or container containing a dietary supplement, 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 this regulation, of that vitamin 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 vitamin in each unit.

19. Minerals—(1) The following dietary supplements may be described as minerals:

Calcium:
Chlorine:
Chromium:
Copper:
Fluorine:
Iodine:
Iron:
Magnesium:
Manganese:
Molybdenum:
Phosphorus:
Potassium:
Selenium:
Sodium:
Zinc.

(2) If the quantity of minerals in a dietary supplement is declared on a label, it shall 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 dietary supplement described 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.

20. Enzymes—The following enzymes may be added to dietary supplements:

Amylase and protease derived from *Aspergillus flavus oryzae* or *Aspergillus niger:*
Bromelin:
Ficin:
Invertase:
Papain:
Pectinase:
Pepsin:
Rennet and protein—coagulating enzymes:
Lactase:
Lipase.

PART III

OFFENCES AND PENALTY

21. Offences and penalty—(1) Every person who contravenes or fails to comply with any of the provisions of regulations 3, 4, 5 (6), 13 (2), 14 (2), 15 (2), 16 (2), 17 (2), and 18 (1) of these regulations commits an offence against these regulations.

(2) Every person who commits an offence against these regulations is liable to a fine not exceeding $500, and, in the case of a continuing offence, to a further fine not exceeding $50 for every day on which the offence has continued.

P. G. MILLEN,
Clerk of the Executive Council.

EXPLANATORY NOTE

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations, in a sense, fill the gap between the Food Regulations 1984 and the Medicines Regulations 1984, in that dietary supplements are not "food" or "medicine" in the ordinary sense of those words. However, they are "food" within the meaning of the Food Act 1981, and will be "related products" within the meaning of the Medicines Act 1981 if therapeutic claims are made for them.

Part I prescribes certain general requirements relating to the manufacture, labelling, and advertising of dietary supplements, and follows broadly the equivalent provisions of Part I of the Food Regulations 1984.

Part II prescribes certain specific requirements relating to food additive standards in respect of certain classes of dietary supplements.

Issued under the authority of the Regulations Act 1936.
Date of notification in *Gazette:* 22 August 1985.
These regulations are administered in the Department of Health.