# SUBSIDIARY LEGISLATION 449.36

## FOOD SUPPLEMENTS REGULATIONS

30th September, 2003

*LEGAL NOTICE 239 of 2003, as amended by Legal Notices 327 of 2005 and 94 of 2007.*

Citation.

**1.** The title of these regulations is the Food Supplements Regulations.

Scope and applicability.

**2.1.** These regulations concern food supplements marketed as foodstuffs and presented as such.

2.2 These regulations shall not apply to medicinal products, as defined in the Medicines Act. Cap. 458.

Definitions.

**3.1.** In these regulations, unless the context otherwise requires, the following definitions shall apply:

(*a*) 'food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;

(*b*) 'nutrients' means the following substances:

(i) vitamins,

(ii) minerals;

(*c*) 'other substances', in the context of paragraph (*a*), shall mean any substances falling within one of the categories listed in the Fourth Schedule.

General provisions.

**4.1** Food supplements may only be marketed if they comply with these regulations.

4.2 Food supplements shall be delivered to the ultimate consumer only in a pre-packaged form.

4.3 Food supplements may only be dispensed by a pharmacist, doctor or a person with other suitable qualifications as may be laid down by the Food Safety Commission.

4.4 In dispensing food supplements, the persons referred to in regulation 4.3 shall ensure that consumers are sufficiently informed about any known negative effects of the supplements, or contra-indications for their use, particularly in the case of pregnant or lactating women and any of the other vulnerable groups indicated in column (*e*) of the Third Schedule.

4.5 Food supplements may not be specifically intended for infants below the age of twelve months unless the manufacturer has detailed evidence establishing the safety of the supplement for that

purpose. Only food supplements specifically intended for infants below the age of twelve months may be dispensed to that category of persons.

Manufacture of food supplements. *Amended by: L.N. 327 of 2005.*

**5.1.** Only vitamins and minerals listed in the First Schedule, in the forms listed in the Second Schedule, may be used for the manufacture of food supplements, subject to regulation 5.4.

5.2 Purity criteria for substances listed in the Second Schedule, specified by other provisions for their use in the manufacture of foodstuffs for purposes other than those covered by these regulations, shall apply.

5.3 For those substances listed in the Second Schedule for which purity criteria are not specified by legislation, and until such specifications are adopted, generally acceptable purity criteria recommended by international bodies shall be applicable.

5.4 Until 31 December 2009, the use of vitamins and minerals not listed in the First Schedule, or in forms not listed in the Second Schedule, is allowed, provided that:

(*a*) the substance in question was used in one or more food supplements marketed in the European Community on 12th July 2002,

(*b*) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements.

5.5 Subject to the provisions of regulation 5.8, food supplements providing a source of any nutrient at a level in excess of the maximum upper level as may be established for that nutrient by the Third Schedule to these regulations may only be sold in Malta subject to a prior approval by the Food Safety Commission.

The Food Safety Commission shall take into account, in particular, the product's presentation, its labelling, any instructions for its use, as well as any other indication or information provided by the manufacturer.

The Food Safety Commission may also make the marketing of such food supplements subject to any conditions it deems appropriate for the purposes of safeguarding public health.

5.6 Subject to the provisions of regulation 5.8, food supplements providing a source of any nutrient at a level in excess of the guidance level as may be established for that nutrient by the Third Schedule may only be marketed if the manufacturer has established that usage of the product does not cause damage to human health when used as instructed by the manufacturer, taking account, in particular of the product's presentation, its labelling, any instructions for its use, as well as any other indication or information provided by the manufacturer. The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in these regulations.

5.7 Food supplements providing a source of any substance

falling within one of the categories listed in the Fourth Schedule, may only be marketed if the manufacturer has established that usage of the product does not cause damage to human health when used as instructed by the manufacturer, taking account, in particular of the product's presentation, its labelling, any instructions for its use, as well as any other indication or information provided by the manufacturer. The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in these regulations.

5.8 The maximum upper levels and the guidance levels for the nutrients prescribed by the Third Schedule are calculated on the basis of an adult body weight of 60 kg. In the case of products specifically intended for, or indicated as suitable for, persons under eighteen years of age, the guidance body weights for each age group shall be those indicated in the Fifth Schedule, and the values in columns (*c*) and (*d*) of the Third Schedule shall be reduced proportionately.

Sale of food supplements. S.L. 449.46

**6.1.** For the purposes of regulation 5.1 of the Labelling, Presentation and Advertising of Foodstuffs Regulations, the name under which products covered by these regulations are sold shall be 'food supplement'.

6.2 The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.

6.3 Nothing in regulation 6.2 shall be construed as preventing the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy.

S.L. 449.46

6.4 Without prejudice to the Labelling, Presentation and Advertising of Foodstuffs Regulations, the labelling shall bear the following particulars:

(*a*) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances;

(*b*) the portion of the product recommended for daily consumption;

(*c*) a warning not to exceed the stated recommended daily dose;

(*d*) a statement to the effect that food supplements should not be used as a substitute for a varied diet;

(*e*) a statement to the effect that the products should be stored out of the reach of young children.

6.5 The labelling, presentation and advertising of food supplements shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

Declaration of nutrients. *Amended by: L.N. 327 of 2005.*

**7.1.** The amount of the nutrients or substances with a nutritional or physiological effect present in the product shall be declared on the labelling in numerical form. The units to be used

for vitamins and minerals shall be those specified in the First Schedule.

7.2 The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling.

7.3 Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned, as the case may be, in the Schedule to the Nutrition Labelling for Foodstuffs Regulations. S.L. 449.20

7.4 The declared values mentioned in regulations 7.1 and 7.2 shall be average values based on the manufacturer's analysis of the product.

7.5 The percentage of the reference values for vitamins and minerals mentioned in regulation 7.3 may also be given in graphical form.

Notification to the competent authority.

**8.1.** To permit efficient official monitoring, when a food supplement is placed on the market for the first time, the manufacturer or the importer shall notify the Food Safety Commission by forwarding a model of the label used for the product.

8.2 In the case of food supplements placed on the market prior to the entry into force of these regulations, the notification prescribed by regulation 8.1 shall take place by not later than 31st December 2004. Food supplements which have not been notified by that date shall be removed from the market at the expense of the manufacturer or importer.

8.3 Where necessary, the Superintendent of Public Health may require the manufacturer or the importer to produce the scientific work and the data establishing the product's compliance with the provisions of these regulations. If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

Safeguard measures.

**9.1.** The Food Safety Commission may, on the advice of the Directorate responsible for foodstuffs within the Malta Standards Authority, temporarily suspend or restrict the marketing of any product which complies with these regulations if he has detailed grounds for establishing that the product endangers human health.

FIRST SCHEDULE

Vitamins and minerals which may be used in the manufacture of food supplements

Vitamins

Vitamin A (µg RE)

Vitamin D (µg)

Vitamin E (mg α-TE)

Vitamin K (µg)

Vitamin B1 (mg)

Vitamin B2 (mg)

Niacin (mg NE)

Pantothenic acid (mg)

Vitamin B6 (mg)

Folic acid (µg)

Vitamin B12 (µg)

Biotin (µg)

Vitamin C (mg)

Minerals

Calcium (mg)

Magnesium (mg)

Iron (mg)

Copper (µg)

Iodine (µg)

Zinc (mg)

Manganese (mg)

Sodium (mg)

Potassium (mg)

Selenium (µg)

Chromium (µg)

Molybdenum (µg)

Fluoride (mg)

Chloride (mg)

Phosphorus (mg)

*Amended by:*
*L.N. 94 of 2007.*

## SECOND SCHEDULE

Vitamin and mineral substances which may be used in the manufacture of food supplements

A. Vitamins

1. VITAMIN A
   - (*a*) retinol
   - (*b*) retinyl acetate
   - (*c*) retinyl palmitate
   - (*d*) beta-carotene
2. VITAMIN D
   - (*a*) cholecalciferol
   - (*b*) ergocalciferol
3. VITAMIN E
   - (*a*) D-alpha-tocopherol
   - (*b*) DL-alpha-tocopherol
   - (*c*) D-alpha-tocopheryl acetate
   - (*d*) DL-alpha-tocopheryl acetate
   - (*e*) D-alpha-tocopheryl acid succinate
4. VITAMIN K
   - (*a*) phylloquinone (phytomenadione)
5. VITAMIN B1
   - (*a*) thiamin hydrochloride
   - (*b*) thiamin mononitrate
6. VITAMIN B2
   - (*a*) riboflavin
   - (*b*) riboflavin 5'-phosphate, sodium
7. NIACIN
   - (*a*) nicotinic acid
   - (*b*) nicotinamide
8. PANTOTHENIC ACID
   - (*a*) D-pantothenate, calcium
   - (*b*) D-pantothenate, sodium
   - (*c*) dexpanthenol
9. VITAMIN B6
   - (*a*) pyridoxine hydrochloride
   - (*b*) pyridoxine 5'-phosphate
10. FOLATE

(*a*) pteroylmonoglutamic acid

(*b*) calcium-L-methylfolate

11. VITAMIN B12

(*a*) cyanocobalamin

(*b*) hydroxocobalamin

12. BIOTIN

(*a*) D-biotin

13. VITAMIN C

(*a*) L-ascorbic acid

(*b*) sodium-L-ascorbate

(*c*) calcium-L-ascorbate

(*d*) potassium-L-ascorbate

(*e*) L-ascorbyl 6-palmitate

B. Minerals

calcium carbonate

calcium chloride

calcium salts of citric acid

calcium gluconate

calcium glycerophosphate

calcium lactate

calcium salts of orthophosphoric acid

calcium hydroxide

calcium oxide

magnesium acetate

magnesium carbonate

magnesium chloride

magnesium salts of citric acid

magnesium gluconate

magnesium glycerophosphate

magnesium salts of orthophosphoric acid

magnesium lactate

magnesium hydroxide

magnesium oxide

magnesium sulphate

ferrous carbonate

ferrous citrate

ferric ammonium citrate

ferrous gluconate

ferrous fumarate
ferric sodium diphosphate
ferrous lactate
ferrous sulphate
ferric diphosphate (ferric pyrophosphate)
ferric saccharate
elemental iron (carbonyl+electrolytic+hydrogen reduced)
ferrous bisglycinate
cupric carbonate
cupric citrate
cupric gluconate
cupric sulphate
copper lysine complex
sodium iodide
sodium iodate
potassium iodide
potassium iodate
zinc acetate
zinc chloride
zinc citrate
zinc gluconate
zinc lactate
zinc oxide
zinc carbonate
zinc sulphate
manganese carbonate
manganese chloride
manganese citrate
manganese gluconate
manganese glycerophosphate
manganese sulphate
sodium bicarbonate
sodium carbonate
sodium chloride
sodium citrate
sodium gluconate
sodium lactate

sodium hydroxide
sodium salts of orthophosphoric acid
potassium bicarbonate
potassium carbonate
potassium chloride
potassium citrate
potassium gluconate
potassium glycerophosphate
potassium lactate
potassium hydroxide
potassium salts of orthophosphoric acid
sodium selenate
sodium hydrogen selenite
sodium selenite
chromium (III) chloride
chromium (III) sulphate
ammonium molybdate (molybdenum (VI))
sodium molybdate (molybdenum (VI))
potassium fluoride
sodium fluoride

THIRD SCHEDULE

Maximum Permitted Levels and Guidance Levels for Vitamins and Minerals

| Reference Number | Nutrient | Maximum Upper Level (per day) on the basis of a 60 kg adult | Guidance Level (per day) on the basis of a 60 kg adult | Vulnerable Groups | Additional Notes |
|---|---|---|---|---|---|
| (a) | (b) | (c) | (d) | (e) | (f) |
| VITAMINS | | | | | |
| 1 | Biotin | - | 0.9 mg | - | - |
| 2 | Folic Acid | - | 1.0 mg | Individuals at risk of vitamin B12 deficiency, in whom folic acid supplementation may mask the haematological signs and symptoms of this deficiency, allowing the associated myeloneuropathy to develop.<br>Patients treated with drugs which interfere with folate metabolism, and in whom folic acid supplementation may be associated with reduced effectiveness of the therapy or increased incidence of side effects. | |
| 3a | Nicotinic acid | - | 17.0 mg | Individuals with hepatic dysfunciton or a history of liver disease, diabetes mellitus, active peptic ulcer disease, gout, cardiac arrhythmias, migraine headaches and alcoholism may be particularly susceptible to nicotinic acid. | This guidance level is based on intakes of conventional formulations of nicotinic acid.<br>Sustained release forms may not be used in food supplements. |
| 3b | Nicotina-mide | - | 500 mg | - | There is a lack of data on the safety of nicotinamide in pregnancy, and there are no relevant animal data. Therefore, this level does not apply to pregnant women. |
| 4 | Pantothenic acid | - | 200 mg | - | - |

| Reference Number | Nutrient | Maximum Upper Level (per day) on the basis of a 60 kg adult | Guidance Level (per day) on the basis of a 60 kg adult | Vulnerable Groups | Additional Notes |
|---|---|---|---|---|---|
| (a) | (b) | (c) | (d) | (e) | (f) |
| 5 | Riboflavin (Vitamin B2) | - | 100 mg | There is a theoretical possibility that neonates undergoing phototherapy for hyperbilirubinaemia may be at risk at this time from photo-activation of riboflavin. | - |
| 6 | Thiamin (Vitamin B1) | - | 100 mg | No potential vulnerable groups have been identified; however, the clinical trials indicate that there is a possibility that a very small number of people may be particularly sensitive (allergic) to thiamin. | This level is applicable to the water-soluble forms of thiamin only. |
| 7 | Vitamin B6 (Pyrido-xine) | 10 mg | - | - | - |
| 8 | Vitamin B12 (Cobala-min) | - | 1mg | - | - |
| 9 | Vitamin C | - | 1000 mg | Individuals unable to regulate iron absorption due to haemochromatosis or thalassaemia may be vulnerable to the enhanced iron absorption caused by vitamin C. | - |

| Reference Number | Nutrient | Maximum Upper Level (per day) on the basis of a 60 kg adult | Guidance Level (per day) on the basis of a 60 kg adult | Vulnerable Groups | Additional Notes |
|---|---|---|---|---|---|
| (a) | (b) | (c) | (d) | (e) | (f) |
| 10a | Vitamin A (Retinol) | - | 1500µg | Retinol may represent a teratogenic risk, particularly within the first trimester of pregnancy.<br>Women who are pregnant or who wish to become pregnant should not take dietary supplements containing vitamin A except on medical advice.<br>Other groups potentially vulnerable to vitamin A toxicity include the young; older people; those suffering from osteoporosis, chronic renal failure, diabetes mellitus or under-nutrition; haemodialysis patients and individuals with compromised liver function. An apparent vitamin A intolerance has been observed on some children. | 1µg Retinol Equivalent = 1µg retinol = 1.78 µg retinyl palmitate = 6 µg β-carotene = 12 µg other carotenoids with provitamin A activity = 3.33 IU vitamin A activity from retinol |
| 10b | β-carotene | 7 mg | - | Groups vulnerable to β-carotene toxicity include current smokers, individuals with previous high-level exposure to asbestos, those with high alcohol intakes, and/or a history of myocardial infarction. | - |

| Reference Number | Nutrient | Maximum Upper Level (per day) on the basis of a 60 kg adult | Guidance Level (per day) on the basis of a 60 kg adult | Vulnerable Groups | Additional Notes |
|---|---|---|---|---|---|
| (a) | (b) | (c) | (d) | (e) | (f) |
| 11 | Vitamin D | - | 0.025 mg | Adults with disease states such as sarcoidosis, Mycobacterium infections and idiopathic hypercalciuria and hypercalcaemia are more vulnerable to hypercalcaemia resulting from moderate vitamin D intakes (>0.025mg/ day). Infants are most at risk of developing hypervitaminosis D; hypercalcaemia has been reported at vitamin D intakes of 0.050 mg/day and above. | - |
| 12 | Vitamin E | 800 IU (727 mg) | - | - | - |
| 13 | Vitamin K<br>Vitamin K1 (phyllo-quinone) | - | 1 mg | Individuals with glucose-6-phosphate dehydrogenase deficiency are more susceptible to the development of methaemoglobanaemia, and this would include oxidative damage caused by menadione (vitamin K3).<br>Infants are vulnerable to vitamin K3 toxicity. | - |
| MINERALS | | | | | |
| 14 | Chromium (trivalent) | - | 9 mg | - | - |
| 15 | Copper | - | 2 mg | Haemodialysis patients and subjects with chronic liver disease are potentially sensitive to copper excess.<br>Children may be at increased risk of copper toxicity due to a combination of efficient uptake and immature biliary excretion. | - |

| Reference Number | Nutrient | Maximum Upper Level (per day) on the basis of a 60 kg adult | Guidance Level (per day) on the basis of a 60 kg adult | Vulnerable Groups | Additional Notes |
|---|---|---|---|---|---|
| (a) | (b) | (c) | (d) | (e) | (f) |
| 16 | Iodine | - | 0.2 mg | Pregnant and lactating women, and neonates are considered to be vulnerable groups as iodine freely crosses the placenta and is expressed in breast milk, and goitre and hypothyroidism have been reported to occur in the offspring of mothers exposed to pharmacological doses of iodine and iodide. | - |
| 17 | Manganese | - | 4 mg (for the general population)<br>0.5 mg (for products intended for the older population) | Anaemic individuals may be vulnerable to the toxic effects of manganese due to the increased absorption that occurs in states of iron deficiency.<br>Groups with impaired biliary clearance, such as patients with liver disease or older people, may also be susceptible to manganese accumulation and toxicity.<br>It has also been reported that ethanol and long-term use of anti-psychotic drugs increases the susceptibility of humans to manganese toxicity. | - |
| 18 | Molybde-num | - | 25µg | - | - |
| 19 | Selenium | - | 0.2 mg | - | - |
| 20 | Zinc | - | 25 mg | Zinc supplementation may increase the levels of glycosylated haemoglobin in diabetics. | - |

| Reference Number | Nutrient | Maximum Upper Level (per day) on the basis of a 60 kg adult | Guidance Level (per day) on the basis of a 60 kg adult | Vulnerable Groups | Additional Notes |
|---|---|---|---|---|---|
| (a) | (b) | (c) | (d) | (e) | (f) |
| 21 | Calcium | - | 1500 mg | Patients with renal failure are particularly susceptible to developing hypercalcaemia when taking calcium supplements. Individuals without renal failure taking diuretics may also be at increased risk. Patients with absorptive or renal hypercalcuria, primary hyperthyroidism and sarcoidosis may have a higher risk of renal stone formation following calcium supplementation. | - |
| 22 | Fluoride | - | 0.01 mg | 8 year old children and younger have a much higher susceptibility to dental fluorosis. | - |
| 23 | Iron | - | 17 mg | Individuals with pre-existing gastrointestinal tract disease or chronic hepatitis, have been shown to be vulnerable to the toxic effects of iron. | - |
| 24 | Magnesium | - | 400 mg | - | - |
| 25 | Phosphorus | - | 250 mg | - | - |

| Reference Number | Nutrient | Maximum Upper Level (per day) on the basis of a 60 kg adult | Guidance Level (per day) on the basis of a 60 kg adult | Vulnerable Groups | Additional Notes |
|---|---|---|---|---|---|
| (a) | (b) | (c) | (d) | (e) | (f) |
| 26 | Potassium | - | 3700 mg | Older people may be vulnerable to potassium toxicity due to reduced physiological resrve in renal function.<br>Individuals with pre-existing renal disease, hyperkalaemia, adrenal insufficiency, acidosis or insulin deficiency are also vulnerable, as are those using certain drugs, such as potassium-sparing diuretics, β-adrenergic blockers, angiotensin-converting enzyme inhibitors, digitalis, non-steroidal anti-inflammatorydrugs, arginine hydrochloride and succinylcholine.<br>Infants may be vulnerable to excessive potassium due to limited renal reserve and immature function. | - |
| 27 | Sodium chloride | - | - | Salt-sensitive persons | Because sodium chloride may have effects at normal dietary intakes in suceptible individuals, it is not recommended for use in supplements. Levels of sodium shall be kept as low as possible unless the manufacturer is able to demonstrate a clear benefit to the consumer from a higher level. |

## FOURTH SCHEDULE

Illustrative List of Categories of Substances other than Nutrients which may be present in Food Supplements

Herbs

Botanical products

Other plant-derived substances

Amino acids

Fatty acids

Enzymes

Organ tissues

Glandular tissues

Constituents, concentrates, metabolites and extracts of plant or animal origin

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## FIFTH SCHEDULE

Guidance Body Weights per Age Bracket

The following shall be taken as guidance body weights for the age brackets indicated, for the purposes of regulation 5.8.

| Age Group (years) | Guidance Body Weight (kg) |
|---|---|
| 1 – 3 | 12 |
| 4 – 6 | 18 |
| 7 – 10 | 24 |
| 11 – 14 | 36 |
| 15 – 17 | 48 |
| 18 + | 60 |

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