



624/2004

Regulation on dietary supplements.

Amendment regulations:

- 1236/2025 **Regulation on the (8th) amendment to Regulation No. 624/2004 on food supplements.**
(/reglugerdir/eftir-raduneytum/umhverfisraduneyti/nr/24693)
- 1284/2021 **Regulation on the (7th) amendment to Regulation No. 624/2004 on food supplements.**
(/reglugerdir/eftir-raduneytum/umhverfisraduneyti/nr/22782)
- 211/2021 **Regulation on the (6th) amendment to Regulation No. 624/2004 on food supplements.**
(/reglugerdir/eftir-raduneytum/umhverfisraduneyti/nr/22383)
- 1043/2017 **Regulation on the (5th) amendment to Regulation No. 624/2004 on food supplements.**
(/reglugerdir/eftir-raduneytum/umhverfisraduneyti/nr/20799)

See all

- [no_624_2004.doc](/media/vidhengi/nr_624_2004.doc) (/media/vidhengi/nr_624_2004.doc)

Article 1.

Scope and general provisions.

This Regulation applies to food supplements as defined in Article 2. However, its provisions do not apply to food supplements intended for export to countries outside the European Economic Area. The Regulation does not apply to medicinal products as defined in the Medicines Act.

Article 2.

Definitions.

The meaning of words in this regulation is as follows:

Food supplements: Foods intended to supplement the normal diet and which have a high proportion of vitamins, minerals or other substances with a nutritional or physiological effect. These substances may be alone or in combination, and are marketed in dosage form, more specifically as capsules, lozenges, tablets, pills and other similar forms, sachets of powder, ampoules of liquid, droppers and other similar forms of liquids and powders intended for oral administration in measured, small doses.

Article 3.

Vitamins and minerals.

In the production of food supplements, only the vitamins and minerals listed in Annex 1 to this Regulation and in the form specified in Annex 2 may be used. However, until 31 December 2009, it is permitted to use vitamins and minerals not listed in Annex 1 or in a form other than that specified in Annex 2, provided that:

| | |
|----|---|
| 1. | The substance in question is used in one or more food supplements marketed in the European Economic Area at the time of entry into force of the regulation. |
| 2. | The European Food Safety Authority (EFSA) has not issued a negative opinion regarding the use of the substance or its use in the relevant form in the production of food supplements. |

Article 4.

Purity.

In cases where the European Union has defined purity for substances in food supplements, the purity of substances used in the production of food supplements shall be in accordance with those definitions. Where the European Union has not set purity requirements for these substances, as they are used in the production of food supplements, these substances shall be subject to rules concerning the purity of the substances when they are used for purposes other than those covered by this Regulation, for example as set out in the Regulation on food additives and the Regulation on baby food for infants and young children. In the absence of European Union rules, the Environment Agency may set as a condition that the purity of substances used in the production of food supplements shall be in accordance with the definitions of the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), the International Council for Standardization (Codex Alimentarius) or the European Pharmacopoeia.

Article 5.

Labels.

In addition to complying with the provisions of the Regulation on the Labelling, Advertising and Presentation of Foods, food supplements covered by this Regulation must be labelled in the following manner:

| | |
|----|---|
| 1. | With the name "Dietary Supplement" in the same field of vision as the name of the product. |
| 2. | With the name of the class of material or materials that characterize the product. |
| 3. | With the recommended daily intake. |
| 4. | With warnings not to consume more of the product than the recommended daily intake. |
| 5. | With a statement that dietary supplements should not be consumed as a substitute for a varied diet. |
| 6. | With a statement that the product should be stored out of the reach and sight of children. |

It is prohibited in the labelling, advertising and presentation of food supplements to state or imply that a sufficient amount of nutrients cannot generally be obtained from a properly composed or varied diet. It is also prohibited to attribute to food supplements the properties of preventing, treating or curing human diseases or to imply such properties.

The Environmental Agency may require or permit special labelling of food supplements to protect vulnerable groups in society.

Article 6.

Nutritional labelling.

The quantity of vitamins, minerals and other substances with a nutritional or physiological effect present in food supplements as they are ready for use and marketed must be indicated, in numerical values, on the packaging. Only the units set out in Annex 1 shall be used for vitamins and minerals and, as appropriate, micrograms (μg), milligrams (mg) or grams (g) for other substances with a nutritional or physiological effect.

The quantity of vitamins and minerals declared in the nutrition declaration shall be the quantity stated on the label as the recommended daily intake. This quantity shall also be expressed as a percentage of the recommended daily intake as appropriate under the Regulation on the nutrition labelling of foodstuffs, Annex V to the Regulation on baby food for infants and young children and Annex VIII to the Regulation on infant formulae and follow-on formulae.

The stated values shall be average values and shall be based either on chemical analysis of the food or on calculations of average values for the ingredients of the food or on calculations of other confirmed and accepted data as provided for in the Regulation on the labelling of the nutritional value of foods.

Article 7.

Operating permit.

Manufacturers, importers and distributors of food supplements must have an operating license in accordance with Article 9 of the Food Act. The application and issuance of operating licenses are governed by the provisions of the Regulation on Hygiene.

Article 8.

Liability of the manufacturer/importer.

The domestic manufacturer or importer is responsible for ensuring that food supplements comply with the provisions of this Regulation and the general provisions on food hygiene. It is prohibited to distribute food supplements that do not comply with the provisions of this Regulation.

Article 9.

Obligation to report.

When a product covered by the provisions of this Regulation is placed on the market for the first time, domestic manufacturers or importers must notify the Environment Agency on specially prepared forms and submit a sample of the product.

Article 10.

Precautionary considerations.

If there is a reasonable suspicion that food supplements covered by this regulation are dangerous to human health, based on new information or a reassessment of existing information that has emerged since the entry into force of the regulation, the Environmental Agency may restrict or prohibit the production, import and sale of the food supplements in question.

Article 11.

Supervision.

Health committees, under the supervision of the Environmental Agency, each in its own area, monitor compliance with the provisions of this regulation, unless otherwise determined by law or special regulations.

Article 12.

Coercive measures.

The scope of authority and coercive measures are governed by Article 30 of the Food Act, No. 93/1995, as amended, cf. and the Act on Hygiene and Pollution Prevention, No. 7/1998.

Article 13.

Penalties.

Penalties are governed by Article 31 of the Food Act, No. 93/1995, cf. and the Act on Hygiene and Pollution Prevention, No. 7/1998.

Article 14.

Entry into force.

This Regulation is established on the basis of the Food Act No. 93/1995, cf. and Act No. 7/1998 on Hygiene and Pollution Prevention, as amended, and for the implementation of Directive 2002/46/EC referred to in Article 54, Chapter XII, Annex II to the Agreement on the European Economic Area. The Regulation shall enter into force upon publication.

Provisional provisions.

I.

Food supplements covered by this regulation that are on the market here at the time the regulation comes into force but do not comply with the provisions of the regulation may be distributed, with a grace period of 1 August 2005.

Ministry of the Environment, July 15, 2004.

Siv Friðleifsdóttir.

Ingimar Sigurdsson.

ANNEX 1

Vitamins and minerals permitted for use in the manufacture of food supplements.

| 1. Vitamins | 2. Minerals |
|-----------------------|--------------------|
| Vitamin A (µg RJ1) | Calcium (mg) |
| Vitamin D (µg2) | Magnesium (mg) |
| Vitamin E (mg a-TJ3) | Iron (mg) |
| Vitamin K (µg) | Copper (µg) |
| Vitamin B1 (mg) | Iodine (µg) |
| Vitamin B2 (mg) | Zinc (mg) |
| Niacin (mg NJ4) | Manganese (mg) |
| Pantothenic acid (mg) | Sodium (mg) |
| Vitamin B6 (mg) | Potassium (mg) |
| Folate (µg) | Selenium (µg) |
| Vitamin B12 (µg) | Chromium (µg) |
| Biotin (µg) | Molybdenum (µg) |
| Vitamin C (mg) | Fluoride (mg) |
| | Chloride (mg) |
| | Phosphorus (mg) |

1 Vitamin A is expressed in retinol equivalents (RE). 1 microgram (µg) RE = 1 µg retinol or 3.33 AE.

2 Vitamin D is calculated as cholecalciferol. 10 micrograms (µg) cholecalciferol or 400 AE.

3 Vitamin E is calculated as alpha-tocopherol equivalents (TE). 1 mg TE = 1 mg d-alpha-tocopherol or 1.49 AE.

4 Niacin is calculated as niacin equivalents (NE). 1 mg NE = 1 mg niacin or 60 mg tryptophan.

ANNEX 2

Vitamins and minerals permitted for use 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 succinic acid

4. VITAMIN K

- a) phyloquinone (phytomenadione)

5. VITAMIN B1

- a) thiamine hydrochloride
- b) thiamine mononitrate

6. VITAMIN B2

- a) riboflavin
- b) sodium riboflavin-5'-phosphate

7. NIACIN

- a) nicotinic acid
- b) nicotinamide

8. PANTOTHENIC ACID

- a) Calcium-D-pantothenate
- b) Sodium-D-pantothenate
- c) Dexpanthenol

9. VITAMIN B6

- a) Pyridoxine hydrochloride
- b) Pyridoxine 5'-phosphate

10. FOLACIN

- a) Pteroylmonoglutamic acid

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 salt 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 sulfate ferrous carbonate ferrous citrate ferric ammonium

citrate ferrous gluconate ferrous fumarate ferric sodium diphosphate ferrous lactate ferrous sulfate ferric diphosphate (ferripyrophosphate) ferric saccharate iron (carbonyl-reduced, electrolytic or hydrogen-oxidized) cupric carbonate cupric citrate cupric gluconate cupric sulfate 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 sulfate manganese carbonate manganese chloride manganese citrate manganese gluconate

manganese glycerophosphate

manganese

sulfate 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 calcium salts of orthophosphoric acid

sodium selenate sodium hydrogen selenite sodium selenite chromium(III) chloride chromium(III) sulfate ammonium

molybdate (molybdenum (VI)) sodium molybdate (molybdenum (VI)) potassium fluoride sodium fluoride

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