NAFDAC Dietary Supplement Regulations, 2025

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Arrangement of Regulations

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Dietary Supplement Regulations, 2025

[ ]

Commencement

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control ('the Governing Council') by Section 30 of the National Agency for Food and Drug Administration and Control Act, Cap. N1, LFN, 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act. Cap. F33. LFN, 2004 and of all the powers enabling it in that behalf, the Governing Council with the approval of the Minister makes the following Regulations: -

Part 1
Objective and Application

1. **Objective**

The objective of these Regulations is to provide regulatory framework for the regulation of dietary supplements manufactured, imported, advertised, sold, displayed for sale, distributed, or used in Nigeria.

2. **Application**

These Regulations apply to dietary supplements manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

Part II
General provisions, Safety and quality requirements, General requirements for labeling of dietary supplement

3. **General provisions**

(1) Dietary supplements shall

(a) be presented to the consumer only in a pre-packaged form.

(b) not bear a medicinal claim.

(c) only contain vitamins and minerals in the forms as listed in the First Schedule to these Regulations for the manufacture of dietary supplements.

(d) not be specifically intended for infants below the age of 12 months.

(2) Notwithstanding regulations 3 (1) (d) to this regulations, dietary supplements may be specifically intended for infants below the age of 12 months where there is significant scientific evidence establishing the safety of the supplement for that purpose.

(3) The labelling, presentation and advertising of dietary supplements shall not attribute to dietary supplements the property of treating or curing a human disease or refer to such properties.

(4) Further to regulations 3 (1) (c) to this regulation, where other dietary ingredients other than vitamins and mineral are used, it shall be as prescribed in the Second Schedule to these Regulations.

(5) Products containing vitamins shall not be at the therapeutic levels. The vitamins and the levels above which they are deemed to be therapeutic are as listed in Third Schedule of these Regulations.

(6) Novel dietary ingredients are not permitted for use in dietary supplements except where there is scientific evidence establishing the safety.

4. **Safety and quality requirements**

(1) Dietary supplements shall comply with the safety and quality requirements provided in these Regulations.

(2) Dietary supplements shall not;

(a) contain any other substances except those stated on the label.

(b) contain any human part or substance derived from any part of the human body.

(c) make any claim to directly or indirectly refer to any diseases and disorder

5. **General requirements for labeling of dietary supplement**

(1) Dietary supplements shall be labelled in accordance with the provisions of the Pre-packaged Food (Labelling)Regulations, 2022.

(2) Pursuant to regulations 5 (1) to this regulation, the label of dietary supplement shall have;

(a) a statement of identity that contains the words "Dietary Supplement." The word "Dietary" may be replaced by the name of the predominant dietary ingredient.

(b) statement of the recommended daily dosage for an adult, both as to quantity and frequency, which shall not exceed the maximum

daily dose and, if the dietary supplement is suitable for children, the recommended daily dose for children shall be stated.

(c) the declaration of the scientific name of the plant if the dietary ingredient is a botanical or the common or usual name standardized in the reference herbs of plant. A statement of the part of the plant used, if a herb or botanical is used shall be declared.

(d) a warning not to exceed the stated recommended daily dose and to avoid overdose.

(e) a statement to the effect that dietary supplements shall not be used as a substitute for a varied diet.

(f) a cautionary statement that the product shall be stored out of the reach of children.

(g) the declaration of the safety information that is considered relevant to the consequences that may result from the use of the supplement where applicable.

(h) declaration of the disclaimers "This statement has not been evaluated by National Agency for Food and Drug Administration and Control" and "This product is not intended to diagnose, treat, or cure any disease", if the supplement bears a claim to affect the structure or function of the body (structure/function claim), a claim of general well-being, or a claim of a benefit related to a classical nutrient deficiency disease.

(i) Where the size, shape or nature of the final product or package does not permit the full listing of labelling information, the use of inserts, leaflets, hang tags, in appropriate format, will be allowed.

6. **Declaration of nutrients**

(1) The amounts of Nutrients and other substances that constitute the supplement shall be declared on the Nutrition information table/Supplement Information Table

(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 label and if different, the amount per unit for single use may also be given.

(1) Information on vitamins and minerals shall also be declared in numerical form and as a percentage of the nutrient reference values/ recommended daily intake

(2) The declared values shall be values based on the manufacturer's analysis of the product.

7. **Contents of vitamins and minerals**

(1) The minimum level of each vitamin and mineral contained in vitamin and mineral dietary supplement per daily portion of consumption as suggested by the manufacturer shall be 15% of the Nutrient Reference Value (NRV)/recommended daily intake as specified in the Fourth Schedule to these Regulations.

(2) Maximum levels of vitamins and minerals contained in vitamin and mineral dietary supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:

(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) the daily intake of vitamins and minerals from other dietary sources.

8. **Packaging**

Dietary supplements shall be packed in packaging material which shall be made only of substances which are safe and suitable for their intended use.

9. **Prohibition**

(1) A dietary supplement shall not be manufactured, imported, exported, advertised, sold or distributed in Nigeria, unless it has been registered in accordance with the provisions of these Regulations.

(2) Dietary Supplements shall not include any of the following:

(a) any product as a sole item of a meal or diet;

(b) any injectable and sterile preparation

(c) any product that is defined otherwise in these regulations

(3) A dietary supplement shall not contain a medicinal ingredient.

Part III
Offences and Penalties, Forfeiture after conviction

10. **Offences and Penalties**

(1) Any person who contravenes any of the provisions of these Regulations commits an offence and shall be liable on conviction. In case of -

(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N800,000.00 or to both; and

(b) a body corporate, to a fine not exceeding N5,000, 000.00.

(2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every: -

(a) director, manager, secretary or other similar officer of the body corporate.

(b) partner or officer of the firm.

(c) trustee of the body concerned.

(d) person concerned in the management of the affairs of the association; or

(e) person who purports to act in a capacity referred to in paragraphs (i) to (iv) of this sub-regulation, is severally liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

11. **Forfeiture after conviction**

(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government:-

(a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence; and

(b) any of the person's property or instruments used in any manner to commit or to facilitate the commission of the offence.

(2) In this section, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

12. **Interpretation**

In these Regulations, unless the context otherwise requires.

Agency means National Agency for Food and Drug Administration and Control.

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.

Packaging material means any form of packaging of dietary supplementary for sale as a single item whether by completely or partially enclosing the dietary supplementary and includes wrappers but does not include leaves traditionally used as food wrappers. A container may enclose several units or types of packages when such is offered to the consumer.

Dietary supplement means is a product (other than tobacco) that

(a) is intended to supplement the diet.
(b) contains one or more dietary ingredients (including vitamins; minerals; herbs or other botanicals; amino acids; and other substances) or their constituents;
(c) is intended to be taken by mouth as a pill, capsule, tablet, or liquid.
(d) is labeled on the front panel as being a dietary supplement.

Ingredient means any substance, 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

Nutrients means the following substances:

(a) vitamins,
(b) minerals.

13. **Citation**

These Regulations may be cited as NAFDAC Dietary Supplement Regulations, 2025.

MADE at Abuja this……..day of …….2025

……..

Dr. Mansur Kabir

Chairman Governing Council

National Agency for Food and Drug Administration and Control (NAFDAC)

First Schedule

Vitamins and Minerals which may be used in the manufacture of Dietary Supplements

Vitamins	**Forms in which they may be used**
Biotin (µg)	D-biotin

Folic acid (µg)	Pteroylmonoglutamate acid
Niacin (Mg NE)	Nicotinic acid Nicotinamide
Pantothenic acid (mg)	D-pantothenate calcium D-pantothenate sodium
Vitamin A (µg RE)	Retinol Retinyl acetate Retinyl palmitate Beta-carotene
Vitamin B1 (mg)	Thiamin hydrochloride Thiamin mononitrate
Vitamin B2 (mg)	Riboflavin Riboflavin 5-phosphate
Vitamin B6 (mg)	Pyridoxine hydrochloride Pyridoxine 5-phosphate
Vitamin B12 (µg)	Cyancobalamin Hydroxocobalamin
Vitamin C (mg)	L-ascorbic acid Sodium-L-ascorbate Calcium-L-ascorbate Potassium-L-ascorbate L-ascorbyl 6-palmitate
Vitamin D (µg)	Cholecalciferol Ergocalciferol
Vitamin E (mg α-TE)	D-alpha-tocopherol DL-alpha-tocopherol D-alpha-tocopheryl acetate DL-alpha-tocopheryl acetate D-alpha-tocopheryl acid succinate
Vitamin K (µg)	Phylloquinone (phytomenadione)
Minerals	**Forms in which they may be used**
Calcium (mg)	Calcium carbonate Calcium chloride Calcium gluconate Calcium glycerophosphate Calcium hydroxide Calcium lactate

	Calcium oxide Calcium salts of citric acid Calcium salts of orthophosphoric
Chronium (µg)	Chromium (III) chloride Chromium (III) sulphate
Copper lysine complex (µg)	Cupric carbonate Cupric citrate Cupric gluconate Cupric sulphate
Iron (mg)	Ferric ammonium citrate Ferric diphosphate (ferric pyrophosphate) Ferric saccharate Ferric sodium diphosphate Ferrous carbonate Ferrous citrate Ferrous fumarate Ferrous gluconate Ferrous lactate Ferrous sulphate
Magnesium (mg)	Magnesium acetate Magnesium carbonate Magnesium chloride Magnesium gluconate Magnesium glycerophosphate Magnesium hydroxide magnesium oxide Magnesium salts of citric acid Magnesium salts of orthophosphoric acid Magnesium lactate Magnesium sulphate Manganese carbonate Manganese chloride Manganese citrate Manganese gluconate Manganese glycerophosphate Manganese sulphate
Potassium (mg)	Potassium bicarbonate Potassium carbonate

	Potassium chloride Potassium citrate Potassium fluoride Potassium gluconate Potassium glycerophosphate Potassium hydroxide Potassium iodide Potassium iodate Potassium lactate Potassium salts of orthophosphoric acid
Sodium (mg)	Sodium iodide Sodium iodate Sodium bicarbonate Sodium carbonate Sodium chloride Sodium citrate Sodium fluoride Sodium gluconate Sodium hydroxide Sodium hydrogen selenite Sodium lactate Sodium molybdate [molybdenum (VI)] Sodium salts of orthophosphoric acid Sodium selenate Sodium selenite
Zinc (mg)	Zinc acetate Zinc chloride Zinc citrate Zinc carbonate Zinc gluconate Zinc lactate Zinc oxide Zinc sulphate

Second Schedule

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

Herbs
Botanical products
Other plant-derived substances
Amino acids
Fatty acids
Enzymes
Organ tissues (non-human)
Glandular tissues (none human)
Constituents, concentrates, metabolites and extracts of plant or animal origin

Third Schedule

Nutrients at Medicinal Levels

Nutrients	**Forms**	**Medicinal level**
Vitamin A	Retinol Retinyl Acetate Retinyl Palmitate	2250ug / 7500IU 2250ug / 7500IU 2250ug / 7500IU
Vitamin D	Cholecalciferol Ergocalciferol	75ug / 0.0075mg / 3000IU 75ug / 0.0075mg / 3000IU
Vitamin K	Phylloquinone (Phytomenadione)	
Niacin	Nicotinic Acid Inositol Hexanicotinate (Inositol Hexaniacinate)	600mg
Folic Acid	Pteroylmonoglutamic Acid	500ug
Vitamin B6	Pyridoxine Hydrochloride	50mg
Vitamin B12	Cyanocobalamin	25ug
	Hydroxocobalamin 25ug	25ug

Fourth Schedule

Vitamin And Mineral Requirements In Human Nutrition

Annex 1

Recommended nutrient intakes — minerals

				Zinc[c] (mg/day)		
Group	Calcium (mg/day)	Selenium (mg/day)	Magnesium (mg/day)	High bioavailability	Moderate bioavailability	Low bioavailability
Infants						
0-6 months	300[d] 400[g]	6	26[d] 36[h]	0.8[d]	2.8	6.6
7 – 12 months	400	10	54	1.1[d] 2.5[j]	4.1	8.4
Children						
1–3 years	500	17	60	2.4	4.1	8.3
4–6 years	600	22	76	2.9	4.8	9.6
7–9 years	700	21	100	3.3	5.6	11.2
Adolescents						
Females 10–18years	1300[k]	26	220	4.3	7.2	14.4
Males 10–18 years	1300[k]	32	230	5.1	8.6	17.1
Adults						
Females 19–50 years (premenopausal)	1000	26	220	3.0	4.9	9.8
51–65 years (menopausal)	1300	26	220	3.0	4.9	9.8
Males19–65 years	1000	34	260	4.2	7.0	14.0
Elderly						
Females 65+ years	1300	25	190	3.0	4.9	9.8
Males 65+ years	1300	33	224	4.2	7.0	14.0
Pregnant women						
First trimester	m	m	220	3.4	5.5	11.0
Second trimester	m	28	220	4.2	7.0	14.0
Third trimester	1200	30	220	6.0	10.0	20.0
Lactating women						
0–3 months	1000	35	270	5.8	9.5	19.0
3–6 months	1000	35	270	5.3	8.8	17.5
7–12 months	1000	42	270	4.3	7.2	14.4

[a] Recommended nutrient intake (RNI) is the daily intake which meets the nutrient requirements of almost all (97.5%) apparently healthy individuals in an age- and sex-specific population.

[d] Breastfed.

[e] Neonatal iron stores are sufficient to meet the iron requirement for the first 6 months in full-term infants. Premature infants and low birth weight infants require additional iron.

[f] Recommendation for the age group 0–4.9 years.

[g] Cow milk-fed.

[h] Formula-fed.

Iron (mg/day)				
15% Bioavailability	12% Bioavailability	10% Bioavailability	5% Bioavailability	Iodine(mg/day)
e	e	e	e	90[f]
6.2[i]	7.7[i]	9.3[i]	18.6[i]	90[f]
3.9	4.8	5.8	116	90[f]
4.2	5.3	6.3	12.6	90[f]
5.9	7.4	8.9	17.8	120 (6–12 yrs)
9.3 (11–14 yrs)[l] 21.8 (11–14 yrs) 20.7 (15–17 yrs) 9.7 (11–14 yrs) 12.5 (15–17 yrs)	11.7 (11–14 yrs)[l] 27.7 (11–14 yrs) 25.8 (15–17 yrs) 12.2 (11–14 yrs) 15.7 (15–17 yrs)	14.0 (11–14 yrs)[l] 32.7 (11–14 yrs) 31.0 (15–17 yrs) 14.6 (11–14 yrs) 18.8 (15–17 yrs)	28.0 (11–14 yrs)[l] 65.4 (11–14 yrs) 62.0 (15–17 yrs) 29.2 (11–14 yrs) 37.6 (15–17 yrs)	150 (13–18 yrs) 150 (13–18 yrs)
19.6	24.5	29.4	58.8	150
7.5	9.4	11.3	22.6	150
9.1	11.4	13.7	27.4	150
7.5	9.4	11.3	22.6	150
9.1	11.4	13.7	27.4	150
n	n	n	n	200
n	n	n	n	200
n	n	n	n	200
10.0	12.5	15.0	30.0	200
10.0	12.5	15.0	30.0	200
10.0	12.5	15.0	30.0	200

[i] Bioavailability of dietary iron during this period varies greatly.

[j] Not applicable to infants exclusively breastfed.

[k] Particularly during the growth spurt.

[l] Pre-menarche.

[m] Not specified.

[n] It is recommended that iron supplements in tablet form be given to all pregnant women because of the difficulties in correctly assessing iron status in pregnancy. In non-anaemic pregnant women, daily supplements of 100 mg of iron (e.g., as ferrous sulphate) given during the second half of pregnancy are adequate. In anaemic women higher doses are usually required.

Annex 2

Recommended nutrient intakes[a] — water- and fat-soluble vitamins

Group	Vitamin C[b] (mg/day)	Thiamine (mg/day)	Riboflavin (mg/day)	Niacin[c] (mg NE/day)	Vitamin B_6 (mg/day)	Pantothenate (mg/day)
	Water-soluble vitamins					
Infants						
0–6 months	25	0.2	0.3	2[i]	0.1	1.7
7–12 months	30	0.3	0.4	4	0.3	1.8
Children						
1–3 years	30	0.5	0.5	6	0.5	2.0
4–6 years	30	0.6	0.6	8	0.6	3.0
7–9 years	35	0.9	0.9	12	1.0	4.0
Adolescents						
Females						
10–18 years	40	1.1	1.0’	16	1.2	5.0
10–18 years	40	1.2	1.3	16	1.3	5.0
Adults						
Females						
19–50 years	45	1.1	1.1	14	1.3	5.0
51–65 years (menopausal)	45	1.1	1.1	14	1.5	5.0
Males 19–65 years	45	1.2	1.3	16	1.3 (19–50 yrs) 1.7 (50+ yrs)	5.0
Elderly						
Females						
65+ years (menopausal)	45	1.1	1.1	14	1.5	5.0
Males 65+ years	45	1.2	1.3	16	1.7	6.0
Pregnant women	55	1.4	1.4	18	1.9	6.0
Lactating women	70	1.5	1.6	17	2.0	7.0

[a] Recommended nutrient intake (RNI) is the daily intake which meets the nutrient requirements of almost all (97.5%) apparently healthy individuals in an age- and sex-specific population.

[c] NE = Niacin equivalents.

[d] DFE = Dietary folate equivalents; mg of DFE provided = [mg of food folate + (1.7 ¥ mg of synthetic folic acid)].

[e] Vitamin A values are “recommended safe intakes” instead of RNIs. See Chapter 2 for further details.

[f] Recommended safe intakes as mg retinol equivalent (RE)/day; conversion factors are as follows:

1 mg retinol = 1 RE
1 mg b-carotene = 0.167 mg RE
1 mg other provitamin A carotenoids = 0.084 mg RE.

Water-soluble vitamins			Fat-soluble vitamins			
Biotin Mg/day	Vitamin B12 Mg/day	Folate d (mg DFE/day	Vitamin A[e,f] (mg RE/day)	Vitamin D (mg/day)	Vitamin E[g] (mg a-TE/day)	Vitamin K[h] (mg/day)
5	0.4	80	375	5	2.7[j]	[k]
6	0.7	80	400	5	2.7[j]	10
8	0.9	150	400	5	5.0[j]	15
12	1.2	200	450	5	5.0[j]	20
20	1.8	300	500	5	7.0[j]	25
25	2.4	400	600	5	7.5	35–55
25	2.4	400	600	5	10.0	35–55
30	2.4	400	500	5	7.5	55
30	2.4	400	500	10	7.5	55
30	2.4	400	600	5 (19–50 yrs) 10 (51–65 yrs)	10.0	65
	2.4	400	600	15	7.5	55
[l]	2.4	400	600	15	10.0	65
30	2.6	600	800	5	[j]	55
35	2.8	500	850	5	[j]	55

[g] Data were not strong enough to formulate recommendations. The figures in the table therefore represent the best estimate of requirements.

[i] Preformed niacin..

[k] This intake cannot be met by infants who are exclusively breastfed. To prevent bleeding due to vitamin K deficiency, all breast-fed infants should receive vitamin K supplementation at birth according to nationally approved guidelines.

[l] Not specified.