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**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL ACT
(CAP. N1 LFN), 2004**

FOOD FORTIFICATION REGULATIONS, 2021



ARRANGEMENT OF REGULATIONS

Regulation :

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SCHEDULES

S. I. No. 67 of 2021

**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL ACT
(CAP. N1, LFN), 2004**

FOOD FORTIFICATION REGULATIONS, 2021

[7th Day of July, 2021]

Commence-
ment.

In exercise of the powers conferred on it by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act (Cap. N1, LFN) 2004 and section 12 of the Food, Drug and Related Products (Registration, Etc.) Act (Cap. F33, LFN) 2004 and all other powers enabling it in that behalf, the Governing Council of the National Agency for Food and Drug Administration and Control with the approval of the Minister of Health makes the following Regulations—

1. These Regulations shall apply to all fortified foods manufactured, imported, exported, distributed, advertised, sold or used in Nigeria.

Scope of
application.

2.—(1) A person shall not—

Prohibition.

(a) sell or advertise any food that is represented on the label to the general public as fortified with vitamins and mineral unless it is registered with the Agency ;

(b) manufacture, import, export, advertise, sell, distribute, store or use any fortified food as treatment, preventive or curative for any of the diseases, disorders or abnormal physical states specified in the First Schedule to these Regulations ;

(c) sell or advertise any food to the general public as fortified with vitamins and minerals referred to in these Regulations, where the Nutrient Reference Value (NRV) intake of that food by a person will result in the NRV by such a person of more than the quantity of vitamins and mineral nutrients specified in Second Schedule to these Regulations ;

(d) in the case of the foods specified in Fourth Schedule to these Regulations, manufacture, import, export, sell, distribute or use, unless it is fortified with vitamin A as prescribed by the Agency.

(2) Food product for the purpose of Global Listing for supermarket items and restaurant operators, shall not be allowed unless it complies with the provisions of these Regulations or as prescribed by the Agency.

(3) Only foods listed in Fifth Schedule to these Regulations may be fortified with the corresponding vitamins or minerals as specified in the same Schedule.

3. A person shall, in advertising a food to which no vitamin or mineral content has been added or on a label of such food, state—

Advertise-
ment of
foods to
which no
Vitamin or
Mineral has
been added.

(a) that the food is “a source” or “a dietary source” of any of the vitamins and mineral nutrient referred to in these Regulations, where reference intake of that food by such person is not less than the level specified in Second Schedule to these Regulations ;

(b) that the food is "a good source" of any of the vitamins and minerals nutrient referred to in these Regulations, where reference intake of that food by a person would result in the daily intake by such person of not less than the amount as specified in Second Schedule to these regulations ; or

(c) that the food is an "excellent source" or an "excellent dietary source" or "excellent diet source" of any of the vitamins and mineral nutrient referred to in these Regulations, where reference intake of that food by a person would result in daily intake by such person of not less than : the amount as specified in the Second Schedule.

Label declaration of food to which Vitamin or mineral has been added.

4.—(1) A person shall not sell a food to which a vitamin has been added unless the amount of the vitamin present in the food is expressed on the label of the food.

(2) Vitamins and minerals can only be declared where they meet the requirements as stipulated in the Second Schedule to these Regulations.

(3) The vitamin and mineral content shall be at least 5% of the NRV per serving, which shall be expressed as a percentage of the NRV per 100g or per 100ml or per package, where the package contains only a single portion and per serving as quantified on the label.

(4) Where vitamins or minerals are present in significant amounts of 15% or higher per serving of food, the conditions in order to qualify for the claim with the prescribed wording for claims shall be provided in Sixth Schedule to these Regulations.

(5) Where nutrient declaration is applied, vitamins and minerals, which are present in amounts less than 5% of the Nutrient Reference Value per 100g or 100ml or per serving as quantified on the label shall not be declared.

Statement relating to mineral content of food.

5. Where the amount of a mineral nutrient referred to in these Regulations is contained in a food is not less than the amount mentioned in the Second Schedule to these Regulations, in advertising that food or on a label of that food, it shall state—

(a) in the case of calcium or phosphorous, that it is a factor in the normal development and maintenance of bones and teeth, especially in infants and children ; and

(b) in the case of calcium, phosphorous or iron, that it is a factor in the maintenance of good health.

Label declaration of food mandatorily fortified with Vitamin A.

6.—(1) A person shall not sell any food, to which vitamin A has been added, unless the amount of the Vitamin A present in the food is expressed on the label of the food and in the quantity as provided in Second Schedule to these Regulations.

(2) Mandatory food fortification with vitamin A shall be as prescribed in Third Schedule to these Regulations.

(3) Flour when fortified, shall contain the micronutrient as provided in the Fourth Schedule to these Regulations.

7. In addition to complying with the Agency's Pre-packaged Food, Water and Ice Labelling Regulations, the following shall apply, the— **Labelling.**

(a) amount of vitamin or mineral nutrient added to the specific quantity of the food shall be declared as percentage daily value on the product label ; and

(b) products stated in Second Schedule shall carry on their label a picture of an eye with A at the centre of the eye to indicate they are fortified with Vitamin A.

8.—(1) Pre-packaged food fortified with vitamin and mineral nutrients shall be packaged and distributed in container that shall safeguard the hygienic, nutritional, organoleptic and other qualities of the product. **Packaging.**

(2) The container, including packaging material, shall be made of substances, which are safe and suitable for their intended use.

(3) All fortified food shall be packaged in a manner that takes into consideration the nature of the fortificant added and its effect on the shelf life of such food.

9.—(1) Any person who contravenes any of the provisions of these Regulations commits an offence and liable on conviction, in the case of— **Offences and Penalties.**

(a) an individual, to imprisonment for a term not exceeding 1 year or to a fine not exceeding ₦800,000.00 or to both ; and

(b) a body corporate, to a fine not exceeding ₦5,000,000.00.

(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 (a) to (d) of this sub-regulation,

is severally liable to be proceeded against and punished for the offence in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

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Forfeiture
after
conviction.

10. 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 instrumentalities used in any manner to commit or to facilitate the commission of the offence.

Revocation.

11.—(1) The Food Fortification Regulations 2005 and Vitamin A Fortification Regulations 2005 are revoked.

(2) The revocation of the Regulations Specified in sub-regulation (1) of this regulation shall not affect anything done or purported to be done under the revoked Regulations.

Enforcement
of these
Regulations.

12. The Agency shall be responsible for the enforcement of these Regulations.

Interpretation.

13. In these Regulations—

“Advertising” means the publicity of goods and description of all products which include any form of notices in circulars, handouts, labels, wrappers, catalogues and price list, billboards, posters, newspapers, magazines and any other document made orally or otherwise or by means of projected light and sound recording ;

“Advertisement” means the publicity of goods and description of all products which include any form of notices in circulars, handouts, labels, wrappers, catalogues and price list, billboards, posters, newspapers, magazines and any other document made orally or otherwise or by means of projected light and sound recording ;

“Agency” means the National Agency for Food and Drug Administration and Control ;

“Food” means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs ;

“Fortificant” means the prescribed compound which provides the specified micronutrient ;

“Fortification” means the addition of vitamins, mineral nutrients or amino acids to a food whether or not it is normally contained in the food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population groups ;

“Fortified Foods” are foods to which vitamins, mineral nutrients or amino acids have been added to for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population groups ;

“*Global Listing*” means a scheme that enables the importation of conventional food and cosmetics items by supermarket operators for retail purposes within approved outlets. Approvals will be granted annually for restricted quantities ;

“*Logo*” means any symbol authorized by the Agency for use on the packaging or label of certain foods to signify approval by the Government ;

“*Micronutrient*” means a natural or synthesized vitamin, mineral, or trace element that is essential for normal growth, development and maintenance of life and of which a deficit will cause characteristic biochemical or physiological changes ;

“*Mineral Nutrient*” means any of the following chemical elements, whether alone or in a compound with one or more other chemical elements :

- (a) calcium,
- (b) phosphorus,
- (c) iron,
- (d) sodium,
- (e) potassium,
- (f) iodine,
- (g) zinc,
- (h) copper,
- (i) magnesium, and
- (j) manganese ;

“*Nutrient Reference Value (NRV)*” means a set of numerical values that are based on scientific data for purposes of nutrition labeling and relevant claims ;

“*Proceeds*” means any property derived or obtained, directly or indirectly, through the commission of the offence ;

“*Testimonial*” with respect to a food that is represented as contained vitamin, mineral nutrient or an amino acid, means any pictorial, written or oral representation as to the result that is, has been or may be, produced by addition to a person’s diet of the vitamin, mineral nutrient, or amino acid, as the case may be ;

“*Vitamin*” means any of the following vitamins or their synonymous names—

- (a) vitamin A (include retinol and retinol derivatives),
- (b) derivatives excluding carotenes),
- (c) vitamin B1 or thiamine,
- (d) vitamin B2 or riboflavin,

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- (e) nicotinic Acid or nicotinamide,
- (f) vitamin B6 or pyridoxine,
- (g) folic acid,
- (h) d-pantothenic acid,
- (i) biotin,
- (j) vitamin B12 or cyanocobalamine,
- (k) vitamin C or L-ascorbic acid, and
- (l) any salt or derivative of a vitamin listed in paragraph (a) to (j) of this regulation ; and

“*Vitamin A*” means any of the following or their synonymous names—

- (a) vitamin A ;
- (b) retinol and retinol derivatives ; and
- (c) any salt or derivative of vitamin A.

Citation.

14. These Regulations may be cited as Food Fortification Regulations, 2021.

FIRST SCHEDULE

[Regulation 2 (1) (b)]

1. Acquired Immune Deficiency Syndrome ;
2. Alcoholism ;
3. Appendicitis ;
4. Arteriosclerosis ;
5. Asthma ;
6. Blood disorder ;
7. Cancer ;
8. Cataract ;
9. Diabetes ;
10. Cholera ;
11. Diphtheria ;
12. Disorder of menstrual flow ;
13. Disorder of prostate gland ;
14. Dysentery ;
15. Encephalitis ;
16. Enteric fever ;
17. Epilepsy ;
18. Erysipelas ;
19. Filariasis ;
20. Gall stones, kidney stones and bladder stones ;
21. Gangrene ;
22. Any genital or urinary diseases not mentioned elsewhere in this schedule ;
23. Glaucoma ;
24. Goiter ;
25. Hay fever ;
26. Heart disease ;
27. Hernia ;
28. High blood pressure ;
29. Infective hepatitis ;
30. Influenza ;
31. Jaundice ;
32. Kidney disease ;
33. Leprosy ;
34. Locomotor ataxis ;
35. Loss of youth ;
36. Measles ;
37. Meningitis ;
38. Mental conditions ;
39. Mumps ;
40. Nervousness ;
41. Nutritional disorders ;
42. Obesity ;

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- 43. Onchocerciasis ;
- 44. Paralysis ;
- 45. Plague ;
- 46. Pleurisy ;
- 47. Pneumonia ;
- 48. Poliomyelitis ;
- 49. Rabies ;
- 50. Rheumatic fever ;
- 51. Schistosomiasis ;
- 52. Sexual impotence, Loss of virility or Sterility ;
- 53. Sleeping sickness ;
- 54. Small pox ;
- 55. Snake bite ;
- 56. Syphilis ;
- 57. Tetanus ;
- 58. Trachoma ;
- 59. Tuberculosis ;
- 60. Tumors ;
- 61. Typhoid fever ;
- 62. Undulant fever ;
- 63. Ulcers of the gastro-intestinal tract ;
- 64. Venereal diseases ;
- 65. Yaws ; and
- 66. Yellow fever.

SECOND SCHEDULE

[Regulation 2 (1) (c), 3 (a) and (c), 4 (2), 5 (1), 6 (c) and 7 (b)]

NUTRIENT REFERENCE VALUES (NRVS)

<i>Vitamins and Minerals</i>	<i>Values</i>
Vitamin A	800 (µg)
Vitamin D	5 (µg)
Vitamin E	9 mg
Vitamin C	100 (mg)
Vitamin B1 (Thiamine)	1.2 (mg)
Vitamin B2 (Riboflavin)	1.2 (mg)
Niacin	15 (mg)
Pyridoxine (B ₆)	1.3 (mg)
Folic Acid	400 (µg)
Vitamin B ₁₂	2.4 (µg)
Biotin	30 (µg)
Pantothenic Acid	5 (mg)
Calcium	1000 (µg)
Vitamin k	60 (µg)
Phosphorus	700 (mg)
Iron	14 (mg)
Magnesium	310 (mg)
Zinc	11 (mg)
Iodine	150 (µg)
Copper	900 (µg)
Selenium	60 (µg)
Manganese	3 (µg)
Molybdenum	45 (µg)

LEVELS OF MANDATORILY FORTIFIED FOODS
WITH VITAMIN A

<i>Vehicle</i>	<i>Level of Fortificant</i>
Sugar	25,000 iu/kg
Wheat and Maize Flour	6000 iu/kg
Vegetable Oil	20,000 iu/kg
Margarine & Butter	26,000 – 33,000 iu/kg

FOURTH SCHEDULE

[Regulation 2 (1) (c) and 6 (2)]

MANDATORY MICRONUTRIENTS REQUIREMENTS FOR WHEAT FLOUR, COMPOSITE FLOUR, MAIZE FLOUR, WHEAT SEMOLINA AND WHOLE MAIZE MEAL

Vitamin A	Dry vitamin A palmitate 250 CWS/SN/CWD	2.0 mg/kg
Vitamin B9	Folic acid Food grade	2.6 mg/kg
Vitamin B12	0.1% CWS/SN/CWD	0.02 mg/kg
Iron	NaFeEDTA (anhydrous in line with FCC)	40.0 mg/kg
Vitamin B2	Riboflavin Fine powder	5.0 mg/kg
Zinc	Zinc oxide	50.0 mg/kg
Vitamin B1	Thiamine Mononitrate	6.0 mg/kg
Vitamin B3	Niacinamide	45.0 mg/kg
Vitamin B6	Pyridoxine Hydrochloride	6.0 mg/kg

FOOD TO WHICH A VITAMIN, MINERAL, NUTRIENT OR
AMINO ACID MAY BE ADDED

S/No	<i>Food Vitamin, Mineral Nutrient or Amino Acid</i>	
1.	Breakfast Cereals	Voluntary: Thiamine, niacin, vitamin B6, folic acid, pantothenic acid, magnesium, iron, zinc
2.	Fruit nectars, fruit drinks and bases concentrates mixes for fruit drink and a mixture of vegetable juices	Voluntary: Vitamin C
3.	Infant Cereal Products	Voluntary: Thiamine, riboflavin, niacin or niacinamide, calcium, phosphorus, iron, iodine
4.	Margarine and other similar substitutes for butter.	Mandatory: Vitamin A, vitamin D Voluntary: Alpha-tocopherol
5.	Alimentary Pastes	Voluntary: Thiamine, riboflavin, niacin or niacinamide, folic acid, pantothenic acid, vitamin B6, iron, magnesium
6.	Enriched Alimentary Pasta	Mandatory: Thiamine, riboflavin, niacin, folic acid, iron Voluntary: Pantothenic acid, vitamin B6, magnesium
7.	Prepared infant formulas and formulated liquid diet	Vitamins - Alpha-tocopherol, biotin, pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin K Minerals - calcium, chloride, copper, chromium, iodide, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc ; Amino Acids - alanine, arginine, aspartic acid, cystine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, taurine, threonine,

		tryptophan, tyrosine, valine (to improve the quality of the protein) Also - other nutritional substances at the same levels found in human milk (for infant formula)
8.	Food represented for use in a very low-energy diet	Mandatory: Vitamins - Alpha-tocopherol, biotin, d-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin K Minerals - Calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc
9.	Flavoured beverage mixes and bases recommended for addition to milk	Voluntary: Vitamin A, thiamine, niacin or niacinamide, vitamin C, iron.
10.	Simulated meat products, simulated poultry meat products, meat product extenders and poultry product extenders	Mandatory: Thiamine, riboflavin, niacin, pyridoxine, d-pantothenic acid, folic acid, vitamin B12, iron, magnesium, potassium, zinc, copper Amino Acids - Histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, valine
11.	Meal replacements and nutritional supplements	Mandatory: Vitamins — alpha-tocopherol, biotin, d-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B6, vitamin B12, vitamin C, vitamin D Minerals — calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc
12.	Ready breakfast, instant breakfast and other similar breakfast replacement foods however described	Mandatory: Vitamin A, thiamine, riboflavin, niacin or niacinamide, vitamin C, iron.

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13.	Milk, milk powder, sterilized milk, (naming the flavour) milk	Voluntary: Vitamin D
14.	Condensed milk	Voluntary: Vitamin D
15.	Skim milk with added milk solids, partly skimmed milk with added milk solids, (naming the flavour) skim milk, (naming the flavour) partly skimmed milk, (naming the flavour) skim milk with added milk solids, (naming the flavour) partly skimmed milk with added milk solids, skim milk, partly skimmed milk, skim milk powder	Voluntary: Vitamin A, vitamin D
16.	Evaporated skim milk, concentrated skim milk, evaporated partly skim milk, concentrated partly skimmed milk	Voluntary: Vitamin A, vitamin C, vitamin D
17.	Evaporated Milk	Voluntary: Vitamin C, Vitamin D
18.	Apple juice, reconstituted apple juice, grape juice, reconstituted grape juice, pineapple juice, reconstituted pineapple juice, apple and (naming the fruit) juice concentrated fruit juice except frozen concentrated orange juice	Voluntary: Vitamin C
19.	Apple juice, reconstituted apple juice, grape juice, reconstituted grape juice, pineapple juice, reconstituted pineapple juice, concentrated fruit juice.	Vitamin C.
20.	Enriched flour Garri, yam flour and other cereals flour	Mandatory: Thiamine, riboflavin, niacin, folic acid, iron Voluntary: Vitamin B6, d-pantothenic acid, calcium, magnesium

21.	Salt, table salt	Mandatory Iodine (in the form of potassium iodide).
22.	Sugar	Mandatory Vitamin A
23.	Vegetable oil	Mandatory Vitamin A

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SIXTH SCHEDULE

[Regulation 4 (4)]

CONDITIONS FOR CLAIMS

<i>Claim</i>	<i>Conditions on food</i>
Source of (Vitamin and Mineral)	At least 5% of NRV per 100g/100ml or per serving
Good Source of (Vitamin and Mineral)	At least 15% of NRV per 100g (solids) or 7.5% of NRV per 100 ml (liquids)
Excellent Source of (Vitamin/Mineral)	At least 30% of NRV per 100g or 100ml solids & Liquids) (at least 2 times the values for “ good source of”)

MADE at Abuja this 7th day of July, 2021.

DR. OSAGIE E. EHANIRE, MD, FWACS
Honourable Minister of Health