

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

FOOD FORTIFICATION REGULATIONS 2019

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Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act Cap NI Laws of the Federation of Nigeria (LFN) 2004 and all 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 Honourable Minister of Health hereby makes the following Regulations:-

1. Scope

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

2. Prohibition

- (1) No person shall
 - 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 Schedule I to these Regulations,
 - c. sell or advertise any food to the general public as fortified with vitamins and minerals referred to in these Regulations, if 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 Schedule II to these Regulations.
 - d. In the case of the foods specified in Schedule IV to this Regulations, no person shall manufacture, import, export, sell, distribute of use, unless it is fortified with vitamin A as prescribed by the Agency.
 - e. No food product for the purpose of Global Listing for Supermarket Items and Restaurant Operators, shall be allowed unless it complies with the provisions of these Regulations or as prescribed by the Agency.
 - f. Only foods listed in Schedule V to these Regulations maybe fortified with the corresponding vitamins and/or minerals as specified in the same Schedule.

3. Advertisement of foods to which no Vitamin and/or Mineral has been added

- (1) A person shall, in advertising a food to which no vitamin and /or mineral content has been added or on a label of such food, state:
 - a. that the food is "a source" or "a dietary source" of any of the vitamins and mineral nutrient referred to in these Regulations, if reference intake of that food by such person is not less than the level as specified in Schedule II to these Regulations
 - b. that the food is "a good source" of any of the vitamins and minerals nutrient referred to in these Regulations, if 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 Schedule II to these regulations
 - 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, if

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 Schedule II to these Regulations

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

- (1) No person shall 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 if they meet the requirements as stipulated in Schedule II to these Regulations
- (3) The vitamin and mineral content must be at least 5% of the NRV per serving which shall be expressed as a percentage of the NRV per 100g or per 100 ml or per package if the package contains only a single portion and per serving as quantified on the label.
- (4) Where vitamins and/or minerals are present in significant amounts of 15% or higher per serving, of food shall meet the conditions in order to qualify for the claim with the prescribed wording for claims as provided in Schedule VI to these Regulations.
- (5) When nutrient declaration is applied, vitamins and minerals which are present in amounts less than 5% of the Nutrient Reference Value per 100 g or 100 ml or per serving as quantified on the label should not be declared.

5. Statement relating to mineral content of food

- (1) Where the amount of a mineral nutrient referred to in these Regulations and that is contained in a food is not less than the amount mentioned in Schedule II, shall in advertising that food or on a label of that food, 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;
 - b. in the case of calcium, phosphorous or iron that it is a factor in the maintenance of good health.

6. Label declaration of food mandatorily fortified with Vitamin A

- (1) No person shall 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 Schedule IV to these regulations
- (2) Flour when fortified, shall contain the micronutrient as provided in Schedule IV to these regulations.

7. Labeling

- (1) In addition to compliance with Pre-packaged Food Labelling Regulations 2019, the following shall apply:
 - a. the amount of vitamin and/or mineral nutrient added to the specific quantity of the food shall be declared as percentage daily value on the product label.
 - b. The products stated in Schedule IV 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. Packaging

(1) Pre-packaged food fortified with vitamin and mineral nutrients shall be;

- (a) packaged and distributed in container that shall safeguard the hygienic, nutritional, organoleptic and other qualities of the product
- (b) the container, including packaging material, shall be made of substances, which are safe and suitable for their intended use.
- (c) 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. Penalty

- (1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of:
 - (a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N50,000 or to both such imprisonment and fine; and
 - (b) a body corporate, to a fine not exceeding N100, 000.
- (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; or
 - (b) partner or officer of the firm or
 - (c) trustee of the body concerned ;or
 - (d) person concerned in the management of the affairs of the association ;or
 - (e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, is severally guilty of that offence and 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.

10. 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;
 - (b) any of the person's property or instrumentalities 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.

11. Interpretation

For the purpose of these Regulations, unless the content otherwise requires:

"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 Reasonable Value; NRV" means a set of numerical values that are based on scientific data for purposes of nutrition labelling and relevant claims.

"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);
- (b) derivatives excluding carotenes);
- (c) vitamin B1 or thiamine;
- (d) vitamin B2 or riboflavine;
- (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.

"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.

12. Repeal of Food Fortification Regulations 2005 and Vitamin A Fortification Regulations 2005

- (1) The Food Fortification Regulations 2005 and Vitamin A Fortification Regulations 2005 are hereby repealed.
- (2) The repeal of these Regulations Specified in Section 12(1) shall not affect anything done or purported to be done under the repealed Regulations.

13. Citation

These Regulations may be cited as Food Fortification Regulations 2019.

SCHEDULE 1

- 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
- 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
- 66. Yellow fever

SCHEDULE II

NUTRIENT REFERENCE VALUES (NRVs)

Vitamins and Minerals	Values
Vitamin A	800 (µg)
Vitamin D	5 (μg)
Vitamin E	9 mg
Vitamin C	100 (mg)
Vitamin B ₁ (Thiamine)	1.2 (mg)
Vitamin B ₂ (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)

SCHEDULE III LEVELS OF MANDATORILY FORTIFIED FOODS WITH VITAMIN A

VEHICLE	LEVEL OF FORTIFICANT
SUGAR	25,000 iu/kg

WHEAT/MAIZE FLOUR	6000 iu/kg
VEGETABLE OIL	20,000 iu/kg
MARGARINE & BUTTER	26,000 – 33,000 iu/kg

SCHEDULE IV

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

SCHEDULE V

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

S/No	FOOD VITA MIN, MINERAL NU	TRIENT OR AMINO ACID
1	Breakfast Cereals	Voluntary: Thiamine, niacin, vitamin B6, folic acid,
		pantothenic acid, magnesium, iron, zinc
2	Fruit nectars, fruit drinks and bases	Voluntary: Vitamin C
	concentrates mixes for fruit drink and	
	a mixture of vegetable juices	
3	Infant Cereal Products	Voluntary: Thiamine, riboflavin, niacin or
		niacinamide, calcium, phosphorus, iron, iodine
4	Margarine and other similar	Mandatory: Vitamin A, vitamin D
	substitutes for butter	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	Vitamins - Alpha-tocopherol, biotin, d-pantothenic
	formulated liquid diet	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	Mandatory: Vitamins - Alpha-tocopherol, biotin,
	low-energy diet	d-pantothenic acid, folic acid, niacin, riboflavin,
	87	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	Voluntary: Vitamin A, thiamine, niacin or
	recommended for addition to milk	niacinamide, vitamin C, iron
10	Simulated meat products, simulated	Mandatory: Thiamine, riboflavin, niacin, pyridoxine,
	poultry meat products, meat product	d-pantothenic acid, folic acid, vitamin B12, iron,
	extenders and poultry product	magnesium, potassium, zinc, copper Amino Acids -
	extenders	Histidine, isoleucine, leucine, lysine, methionine,
		phenylalanine, threonine, tryptophan, valine
11	Meal replacements and nutritional	Mandatory: Vitamins alpha-tocopherol, biotin,
	supplements	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	Mandatory: Vitamin A, thiamine, riboflavin, niacin
	other similar breakfast replacement	or niacinamide, vitamin C, iron
	foods however described	
13	Milk, milk powder, sterilized milk,	Voluntary: Vitamin D
	(naming the flavour) milk	
14	Condensed milk	Voluntary: Vitamin D
15	Skim milk with added milk solids,	Voluntary: Vitamin A, vitamin D
13	partly skimmed milk with added milk	Voluntary. Vitainin 11, Vitainin 12
	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	
16	Evaporated skim milk, concentrated	Voluntary: Vitamin A, vitamin C, vitamin D
	skim milk, evaporated partly skim	
	milk, concentrated partly skimmed	
	milk	
17	Evaporated Milk	Voluntary: Vitamin C, Vitamin D
18	Apple juice, reconstituted apple juice,	Voluntary: Vitamin C
	grape juice, reconstituted grape juice,	-
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	pineapple juice, reconstituted	
	pineapple juice, apple and (naming the	
	fruit) juice concentrated fruit juice	
	except frozen concentrated orange	
	juice	
19	Apple juice, reconstituted apple juice,	Vitamin C.
	grape juice, reconstituted grape juice,	
	pineapple juice, reconstituted	
	pineapple juice, concentrated fruit	
	juice.	
20	Enriched flour	Mandatory: Thiamine, riboflavin, niacin, folic acid,
		iron
	Garri, yam flour and other cereals	Voluntary: Vitamin B6, d- pantothenic acid, calcium,
	flour	magnesium
21	Salt, table salt	Mandatory Iodine (in the form of potassium iodide).
22	Sugar	Mandatory Vitamin A
23	Vegetable oil	Mandatory Vitamin A

SCHEDULE VI CONDITIONS FOR CLAIMS

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

MADE at Abuja this......day of......2019

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Inuwa Abdulkadir Esq Chairman Governing Council

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