



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

FOOD FORTIFICATION REGULATIONS 2018

**COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS
(ending 29th August, 2018).**

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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

No person shall -

- (1) 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.
- (2) 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,
- (3) 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.
- (4) In the case of the foods specified in Schedule IV to this Regulations, no person shall manufacture, import, export, sell, distribute or use, unless it is fortified with vitamin A as prescribed by the Agency.

3. Vitamin content of food

Where the amount of a vitamin referred to in these Regulations contained in a food is not less than the amount mentioned in these Regulations in respect of that vitamin, a person shall in advertising that food or on a label of that food indicate;

- (1) in the case of vitamin C, that it is a factor in the normal development and maintenance of bones, cartilage, teeth and gums; and

- (2) in the case of any of the vitamins listed in these Regulations that it is a factor in the maintenance of good health.

4. Advertisement of foods to which no vitamin has been added

The advertisement of a food to which no vitamins is added shall state:

- (1) that the food is "a source" or "a dietary source" of any of the vitamins referred to in these regulations, if a reasonable Nutrient Reference Value by such person is not less than:
- (a) in the case of Vitamin A, 625 International Units,
 - (b) in the case of Vitamin B1, 0.3 milligram,
 - (c) in the case of Vitamin B2, 0.4 milligram,
 - (d) in the case of nicotinic acid, 5.0 milligrams,
 - (e) in the case of Vitamin C, 7.5 milligrams;
- (2) that the food is "a good source" of any of the vitamins referred to in these regulations, if a NRV by a person would result in the NRV of not less than:
- (a) in the case of Vitamin A, 1,250 International Units,
 - (b) in the case of Vitamin B1, 0.6 milligram,
 - (c) in the case of Vitamin B2, 0.8 milligram,
 - (d) in the case of nicotinic acid, 10.0 milligrams,
 - (e) in the case of Vitamin C, 15 milligrams;
- (3) that the food is an "excellent source" or an "excellent dietary source" or "excellent diet source" of any of the vitamins referred to in these Regulations, if a NRV of that food by a person would result in NRV of not less than:
- (a) in the case of Vitamin A, 2,664 International Units,
 - (b) in the case of Vitamin B1, 1.20 milligrams,
 - (c) in the case of Vitamin B2, 1.8 milligrams,
 - (d) in the case of Nicotinic acid, 19.8 milligrams,
 - (e) in the case of Vitamin C, 30.0 milligrams.

5. Advertising/ Labelling of food to which vitamin has been added

The advertisement of a food to which a vitamin has been added shall state that the food contains the added vitamin that it contained in a specified quantity of the food.

6. Label declaration of food to which vitamin has been added

No person shall sell a food to which a vitamin has been added unless –

- (1) the amount of the vitamin present in the food is expressed on the label of the food; and
- (2) in the case of Vitamin A the amount of the Vitamin A present in the food is expressed on the label of the food in International Unit (I.U.) or in mg/kg.
- (3) in the case of Vitamin B1, Vitamin B2, Nicotinic acid, Vitamin B6, D-pantothenic acid, Vitamin B12, Vitamin C or Vitamin K1, it shall be declared in milligrams per one hundred grams/milliliters of the food; together with the name of the vitamin.
- (4) In the case of Vitamin A, the products stated in the Fourth Schedule shall carry on their label a picture of an eye with A at the center of the eye to indicate they are fortified with Vitamin A.

7. Label declaration in children's food to which no vitamin has been added

Where a food for sale to which no vitamins has been added is represented as being solely for use in the feeding of children under two years of age, the label shall state the amount of any of the vitamins referred to in these regulations that are present in the food, if a NRV of that food by a child under two years of age would result in the NRV by such child of not less than:

- (1) in the case of Vitamin A, 625 international units;
- (2) in the case of Vitamin B1, 0.40 milligram;
- (3) in the case of Vitamin B2, 0.6 milligram;
- (4) in the case of Nicotinic acid, 6.8 milligrams;
- (5) in the case of Vitamin B6, 0.25 milligram; and
- (6) in the case of Vitamin C, 15 milligrams.

8. Vitamin fortification in food for children under two years

Where a food to which a vitamin has been added is to be represented as being solely for use in the feeding of children under two years of age, no person shall sell such food, unless a NRV of that food by a child under two years of age would result in the NRV by the child of not less than:

- (1) in the case of Vitamin A, 833 international units;
- (2) in the case of Vitamin B1, 0.5 milligram;
- (3) in the case of Vitamin B2, 0.8 milligram;
- (4) in the case of Nicotinic acid, 9 milligrams;
- (5) in the case of Vitamin B6, 0.6 milligram; and
- (6) in the case of Vitamin C, 20 milligrams.

9. Minimum quantity of vitamin in food to which vitamin has been added

Notwithstanding the provisions of Regulations 8, no person shall sell a food to which any of the vitamins referred to in these Regulations have been added, unless the NRV of that food by a person would result in the NRV by such person of not less than:

- (1) in the case of Vitamin A, 875 international units;
- (2) in the case of Vitamin B2, 1.4 milligrams;
- (3) in the case of Vitamin B1, 0.9 milligram;
- (4) in the case of Nicotinic acid, 15 milligrams; and
- (5) in the case of Vitamin C, 22.5 milligrams.
- (6) In the case of Vitamin A, it shall be formulated in a way that will ensure the bioavailability of the Vitamin A to the consumer.

10. Maximum quantity of vitamin in fortified food

No person shall sell a food to which any of the vitamin referred to in this regulation have been added, if the NRV of that food by a person would result in the NRV by such a person of more than:

- (1) in the case of Vitamin A, 5,000 International units;
- (2) in the case of Vitamin B1, 1.5 milligrams;
- (3) in the case of Vitamin B2, 1.7 milligrams;
- (4) in the case of Nicotinic acid, 19.6 milligrams;
- (5) in the case of Vitamin B6, 2.0 milligrams; and
- (6) in the case of Vitamin C, 60 milligrams.

11. Labelling nutritional and health claims for vitamins

- (1) Nutritional claims shall be
 - (a) based on science and supported by sound and scientific evidence.
 - (b) it shall have permitted nutrients contained in the final product shall be in a quantity as defined under the conditions given in Schedule
 - (c) the nutrient for which the claim is made shall be in a form that is available to be used by the body.
- (2) Health claims shall be based on current relevant scientific evidence and the level of proof must be sufficient to substantiate that type of claim and the relationship to health
- (3) Any statement in advertising a food that is represented as containing a vitamin or on a label of such food which:

- (a) gives any assurance or guarantee of any kind with respect to the result that may be, has been or will be, obtained by the addition of the vitamin to a person's diet; or
- (b) refer to reproduce or quotes any testimonial, shall be deemed to contravene the provisions of these Regulations.

12. Advertising or labelling of food mineral content

Any statement, in advertisement for, or on a label of a food for sale, relating to or based on the mineral nutrient content of that food not conforming to Regulations 13 to 21 of these Regulations, shall be deemed to contravene the provisions of these Regulations.

13. Statement relating to mineral content of food

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 Section 15 in respect of that mineral nutrient, a person shall, in advertising that food or on a label of that food, state:

- (1) 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;
- (2) in the case of calcium, phosphorous or iron that it is a factor in the maintenance of good health.

14. Advertisement of food to which no mineral nutrient has been added

A person shall, in advertising a food to which no mineral nutrient has been added or on a label of such food, state:

- (1) that the food is "a source" or "a dietary source" of any of the mineral nutrients referred to in these regulations, if a reasonable NRV of that food by a person would result in the NRV by that person of not less than:
 - (a) in the case of calcium, 112 milligrams,
 - (b) in the case of phosphorous, 112 milligrams,
 - (c) in the case of iron, 2 milligrams;
- (2) that the food is a "good source" or "a good dietary source" of any of the mineral nutrients referred to in these regulations, if a reasonable NRV of that food by a person would result in the NRV by such person of not less than:
 - (a) in the case of calcium 225 milligrams,
 - (b) in the case of phosphorous, 225 milligrams,
 - (c) in the case of iron, 4 milligrams.

- (3) that the food is "an excellent source" or "an excellent dietary source" or any of the nutrients referred to in these regulations, if a reasonable NRV of that food by a person would result in the NRV by such a person of not less than:
- (a) in the case of calcium 500 milligrams,
 - (b) in the case of phosphorous, 500 milligrams,
 - (c) in the case of iron, 9 milligrams.

15. Advertisement of food to which Mineral nutrient has been added

Notwithstanding the provision of the Food Products (Advertisement) Regulations 2018, a person shall, in advertising a food to which a mineral nutrient has been added or on a label of such food, state:

- (1) that the food contains the added mineral nutrient; and
- (2) the amount of the added mineral nutrient that is contained in a specified quantity of the food.

16. Labelling of food to which mineral nutrient has been added

- (1) No person shall sell any food, to which a mineral nutrient has been added, unless the amount of the mineral nutrient present in the food is expressed on the label of the food:-
 - (a) by using the name for that mineral nutrient; and
 - (b) in milligrams per one hundred grams or milliliters of the food.

17. Label declaration of mineral nutrients in food to which no mineral nutrients have been added for children

Where a food for sale to which no mineral nutrient has been added is represented as being solely for use in the feeding of children under two years of age, a person may state on the label of the food the amount of any mineral nutrients referred to in these regulations that are present in the food, if a reasonable NRV of that food by a child under two years of age would result in the NRV by the child of not less than:

- (1) in the case of Calcium, 340 milligrams;
- (2) in the case of Phosphorus, 340 milligrams;
- (3) in the case of iron, 6 milligrams;
- (4) in the case of iodine, 0.05 milligrams.

18. Labelling claims for mineral nutrient

- (1) Any statement in advertising a food that is represented as containing a mineral nutrient or on a label of such food, which:
 - (a) gives any assurance or guarantee of any kind with respect to the result that may be, has been or will be obtained by the addition of the mineral nutrient to a person's diet; or
 - (b) refers to, reproduce or quotes, any testimonial, shall be deemed to contravene the provisions of these regulations.

19. Maximum quantity of mineral nutrients, in fortified food.

No person shall sell a food to which any of the mineral nutrient referred to in these regulations has been added unless a reasonable NRV of that food by a person would result in the NRV by the person of not more than:

- (1) in the case of Calcium, 500 milligrams;
- (2) in the case of Phosphorus, 500 milligrams;
- (3) in the case of iron, 9 milligrams;
- (4) in the case of iodine, 0.10 milligrams.

20. Food to which vitamins, minerals, nutrients and amino acids may be added

- (1) No person shall sell a food to which a vitamin, mineral nutrient or an amino acid has been added unless the food is listed in column 1 of the Third Schedule to these regulations and the vitamin, mineral nutrient or amino acid, as the case may be, is listed opposite thereto in Column 2 of the said schedule.
- (2) Notwithstanding the provision of these Regulation, fortification of food with vitamins, mineral nutrients or amino acid shall be by the approval of the Agency.

21. Packaging

Pre-packaged food fortified with vitamin and mineral nutrients shall be –

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

22. Labelling

- (1) Pre-packaged food fortified with vitamin, mineral or both nutrient shall be labelled in accordance with the Pre-packaged food (Labelling) Regulations 2018 of the Agency.
- (2) Notwithstanding the provisions of these Regulations, the amount of vitamin and/or mineral nutrient added to the specific quantity of the food shall be declared in metric system of measurement on the product.
- (3) Net weight/volume shall be declared in metric system of measurement.

23. 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 50,000 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.

24. 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.

25. 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;

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

"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

"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;

"Reasonable NRV" means the amount of that food that is normally take=56

"Recommended NRV" means approximately the upper limit of requirement of vitamin or mineral nutrient in a healthy human being;

"Testimonial" (with respect to a food that is represented as containing 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 riboflavin;
- (e) nicotinic Acid or nicotinamide;
- (f) vitamin B6 or pyridoxine;
- (g) folic acid;
- (h) d-pantothenic acid;
- (i) biotin;
- (j) vitamin B12 or cyanocobalamin;
- (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.

26. Repeal of Food Fortification Regulations 2005

- (1) The Food Fortification Regulation 2005 is hereby repealed.
- (2) The repeal of the Regulations Specified in Section 26 (1) of these Regulation shall not affect anything done or purported to be done under the repealed Regulations.

27. Citation

These Regulations may be cited as Food Fortification Regulations 2018.

FIRST SCHEDULE

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

SECOND SCHEDULE
RECOMMENDED NRV

<i>Vitamins and Minerals</i>	<i>Recommended NRV</i>
Vitamin A	5,000 I. U
Vitamin D	400 I. U
Vitamin E	30 I. U
Vitamin C	60mg
Vitamin B1 (Thiamine)	1.5mg
Vitamin B2 (Riboflavin)	1.7mg
Niacin	20mg
Pyridoxine (B6)	2mg
Folic Acid	0.4mg
Vitamin B12	6mcg
Biotin	0.3mg
Pantothenic Acid	10mg
Calcium	1,000mg
Phosphorus	1,000mg
Iron	18mg
Magnesium	400mg
Zinc	15mg
Iodine	150mcg
Copper	2mg

THIRD SCHEDULE

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

S/NO	FOOD	Vitamin, Mineral Nutrient or Amino acid ¹
1	Breakfast Cereals	Vitamin B1, Vitamin B2, Nicotinic acid, Iron
2	Fruit nectars, fruit drinks bases concentrates mixes for fruit drink and a mixture of vegetable juices	Vitamin C
3	Infant cereal product	Vitamin B1, vitamin B2, nicotinic acid, calcium, phosphorus, iron and iodine
4	Margarine and other similar substitutes for butter	Vitamin B1, vitamin B2, nicotinic acid and iron
5	Alimentary Pastes	Vitamin B1, vitamin B2, nicotinic acid and iron
6	Prepared infant formulas	Vitamin A, vitamin C, vitamin B1, vitamin B2, nicotinic acid, vitamin B6, D-pantothenic Acid, folic acid, vitamin B12, calcium phosphorous, iron, Sodium, Potassium, Iodine, Zinc, Copper, Manganese, Lysine, Methionine tryptophan, Biotin
7	Flavoured beverage mixes and bases recommended for addition to milk	Vitamin A, vitamin B1, nicotinic acid
8	Represented as milk or fish substitutes	Lysine A, methionine
9	Ready breakfast, instant breakfast and other similar breakfast replacement foods	Vitamin A, vitamin B1, vitamin B2, nicotinic acid, vitamin C, iron
10	Condensed milk, standard milk, sterilized milk, ultra-high temperature heat treated milk, milk powder	Vitamin D
11	Reconstituted milk, partly skimmed milk powder any flavoured skimmed milk	Vitamin A

12	Evaporated Milk	Vitamin C
13	Evaporated skim Milk	Vitamin A, Vitamin C
14	Apple juice, reconstituted apple juice, grape juice, reconstituted grape juice, pineapple juice, reconstituted pineapple juice concentrated fruit juice	Vitamin c
15	Enriched flour, garri, yam flour and other cereals flour	Vitamin A, Vitamin B1, Vitamin B2, Nicotinic acid, Calcium, Iron, Vitamin C
16	Salt, table salt	Iodine(in the form of potassium iodine)

FOURTH SCHEDULE

VITAMIN A FORTIFICATION OF SOME FOOD VEHICLE LEVEL OF FORTIFICANT (I.U/KG)

SUGAR	25,000
WHEAT/MAIZE FLOUR	30,000
VEGETABLE OIL	20,000
MARGARINE & BUTTER	26,000 – 33,000

MADE at Abuja this.....day of.....2018

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Inuwa Abdulkadir Esq
Chairman Governing Council

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