

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

**FOOD FORTIFICATION REGULATIONS 2018**

**COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 DAYS.**

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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 whether or not manufactured, imported, exported, distributed, advertised, sold or used in Nigeria.

1. **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 Vitamin A, no person shall manufacture, import, export, advertise, sell, distribute or use any food specified in Schedule IV to these Regulations, unless it is fortified with Vitamin A as prescribed by the Agency***.***
5. **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;

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.
3. **Advertisement of foods to which no vitamin has been added**

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

* + - 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:
    1. in the case of Vitamin A, 625 International Units,
    2. in the case of Vitamin B1, 0.3 milligram,
    3. in the case of Vitamin B2, 0.4 milligram,
    4. in the case of nicotinic acid, 5.0 milligrams,
    5. in the case of Vitamin C, 7.5 milligrams;

1. 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:
   * 1. in the case of Vitamin A, 1,250 International Units,
     2. in the case of Vitamin B1, 0.6 milligram,
     3. in the case of Vitamin B2, 0.8 milligram,
     4. in the case of nicotinic acid, 10.0 milligrams,
     5. in the case of Vitamin C, 15 milligrams;
2. 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:
   * 1. in the case of Vitamin A, 2,664 International Units,
     2. in the case of Vitamin B1, 1.20 milligrams,
     3. in the case of Vitamin B2, 1.8 milligrams,
     4. in the case of Nicotinic acid, 19.8 milligrams,
     5. in the case of Vitamin C, 30.0 milligrams.
3. **Advertising/Labelling of food to which vitamin has been added**

A person shall in advertising a food to which a vitamin has been added or on a label of such food, state that the food contains the added vitamin that it contained in a specified quantity of the food.

1. **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 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.
5. **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, a person shall state, on the label of the food, 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.

1. **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.

1. **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. bin 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.

1. **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.

1. **Labelling nutritional and health claims for vitamins** 
   * + 1. Nutritional claims shall be
2. based on science and supported by sound and scientific evidence.
3. it shall have permitted nutrients contained in the final product shall be in a quantity as defined under the conditions given in Schedule
4. the nutrient for which the claim is made shall be in a form that is available to be used by the body.
5. 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
6. Any statement in advertising a food that is represented as containing a vitamin or on a label of such food which:
   1. 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
   2. refer to reproduce or quotes any testimonial, shall be deemed to contravene the provisions of these Regulations.
7. **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.

1. **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.

1. **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:

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:

* + 1. in the case of calcium, 112 milligrams,
    2. in the case of phosphorous, 112 milligrams,
    3. in the case of iron, 2 milligrams;

1. 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:
   * 1. in the case of calcium 225 milligrams,
     2. in the case of phosphorous, 225 milligrams,
     3. in the case of iron, 4 milligrams.
2. 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:
   * 1. in the case of calcium 500 milligrams,
     2. in the case of phosphorous, 500 milligrams,
     3. in the case of iron, 9 milligrams.
3. **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.

1. **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:-
   1. by using the name for that mineral nutrient; and
   2. in milligrams per one hundred grams or milliliters of the food.
2. **Label declaration of Mineral** n**utrients 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.

1. **Labelling claims for mineral nutrient**
2. Any statement in advertising a food that is represented as containing a mineral nutrient or on a label of such food, which:
   1. 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
   2. refers to, reproduce or quotes, any testimonial, shall be deemed to contravene the provisions of these regulations.
3. **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.

1. **Food to which Vitamins, Minerals, Nutrients and Amino Acids may be added**
2. 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 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.
3. Notwithstanding the provision of these Regulation, fortification of food with vitamins, mineral nutrients or amino acid shall be by the approval of the Agency.
4. **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.

1. **Labelling** 
   1. Pre-packaged food fortified with vitamin and or mineral 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.
2. **Penalty** 
   * 1. Any person who contravenes any of the provisions of these Regulations, shall be guilty of an offence and liable on conviction in the case of -
3. 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;
4. body corporate, to a fine not exceeding N100, 000.
   * 1. Where an offence under these regulations is committed by a body corporate, firm or other association of individuals every:-
   1. director, manager, secretary or other similar officer of the body corporate; or
   2. partner or officer of the firm; or
   3. trustee of the body concerned; or
   4. person concerned in the management of the affairs of the association; or
   5. 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.
5. **Forfeiture**

In addition to the penalty specified in Regulation 23 of these regulations, a person convicted of an offence under these regulations shall forfeit to the Agency the food products and whatsoever is used in connection with the commission of the offence.

1. **Interpretation**

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

1. **"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;
2. "**Agency"** means the National Agency for Food and Drug Administration and Control.
3. **“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;
4. **“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
5. **"Mineral Nutrient"** means any of the following chemical elements, whether alone or in a compound with one or more other chemical elements:
   1. calcium;
   2. phosphorus;
   3. iron;
   4. sodium;
   5. potassium;
   6. iodine;
   7. zinc;
   8. copper;
   9. magnesium; and
   10. manganese;
6. **"Reasonable NRV" means the amount of that food that is normally taken;**
7. **"Recommended NRV"** means approximately the upper limit of requirement of vitamin or mineral nutrient in a healthy human being;
8. **"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;
9. **"Vitamin"** means any of the following vitamins or their synonymous names -
   1. vitamin A (include retinol and retinol);
   2. derivatives excluding carotenes);
   3. vitamin B1 or thiamine;
   4. vitamin B2 or riboflavine;
   5. nicotinic Acid or nicotinamide;
   6. vitamin B6 or pyridoxine;
   7. folic acid;
   8. d-pantothenic acid;
   9. biotin;
   10. vitamin B12 or cyanocobalamine;
   11. vitamin C or L-ascorbic acid; and
   12. any salt or derivative of a vitamin listed in paragraph (a) to (j) of this regulation.
10. **Repeal of Food Fortification Regulations 2005**
11. The Food Fortification Regulation 2005 is hereby repealed.
12. The repeal of the Regulations Specified in Section 27 (i) of this regulation 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 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**

|  |  |
| --- | --- |
| ***Vitamins and Minerals*** | ***Recommended NRV*** |
| 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 acid1** |
| 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 BI, 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 BI, 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

**………………………..**

**Inuwa Abdulkadir Esq**

**Chairman Governing Council**

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