

Government of the People's Republic of Bangladesh
Bangladesh Food Safety Authority

Draft Notification

Date:

S.R.O No. /- In the exercise of the power conferred by section 87 of the Food Safety Act, 2013 (Act No. 43 of 2013), the Bangladesh Food Safety Authority, with prior approval of the Government, make the following regulations, namely: -

1. Title and commencement:- (1) These regulations may be called the Food Fortification Regulations, 2023.

(2) These regulations shall come into force with an immediate effect.

2. Definitions: - Unless there is anything repugnant to the subject or context, in these regulations-

- (1) Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and/or the maintenance of life and which cannot be synthesized in adequate amounts by the body.
- (2) Edible oil means any refined or crude vegetable oil for human consumption, such as soybean oil, palm oil, palm olein, etc. or any other vegetable oil internationally recognized as edible oil.
- (3) Fortification means deliberately increasing the content of essential micronutrients in food to improve the nutritional quality of food and to provide public health benefits with minimal risk to health.
- (4) Fortificant means a substance added to food to provide micronutrients but doesn't include Nutraceuticals or foods for Special dietary uses.
- (5) Government Funded Program means any program, policy, scheme or other provision under which food is sold, distributed or otherwise made available to the public by government of Bangladesh.
- (6) Fortified food means food that underwent the fortification process as per the regulations.
- (7) Micronutrients means essential dietary nutrients including vitamins, minerals or trace elements that are required in very small quantities and are vital to the development, disease prevention and well-being of human beings.
- (8) Mandatory nutrient addition is when the Government of Bangladesh, requires food manufacturers to add specified essential nutrients to foods or food categories through any law/provisions/guidelines.
- (9) Nutrition Claim means any representation which states, suggests, or implies that a food has nutritional properties which are not limited to the energy value but include protein, fat, carbohydrates, vitamins and minerals.



- (10) Refined Iodized Salt – Refined iodized salt is solar/rock salt from which soluble and insoluble impurities are reduced by employing mechanical washing, centrifuging and iodizing, drying, sieving, coating with permitted anticaking agents. It shall be free from visible contamination from clay, grit or other extraneous adulterants or impurities.
- (11) Recommended Daily Intake means the average daily dietary nutrient intake level which is sufficient to meet the nutrient requirement of nearly all (97-98%) of the healthy individuals of a particular life stage and gender group.
- (12) Staple food means articles of food intended for mass consumption daily and include rice, wheat, wheat flour (Atta), refined wheat flour (Maida), edible oil, salt, milk, and such other articles of food as may be designated staple foods under these regulations.
- (13) Vacuum-Evaporated Iodized Salt – Vacuum-evaporated iodized salt is made by evaporating brine employing forced evaporators operating under vacuum, centrifuging, iodizing, drying and coating with permitted anticaking agents. It shall be free from visible contamination from clay, grit or other extraneous adulterants or impurities.
- (14) Voluntary nutrient addition is when food manufacturers add specified essential nutrients to certain foods or food categories as per the schedules under these regulations.
- (15) Quality Assurance means the systematic measures applied and steps taken by manufacturers and packers of fortified food throughout the manufacturing or packing process to ensure that the finished food complies with the provisions of the Act and Regulations and Standards specified thereunder.
- (16) Traditional/Mechanical Iodized Salt – Iodized salt is solar/rock salt mixed with iodizing chemicals and dried if required. Material shall be a crystalline solid, white or pale pink and light grey in color. It shall be free from visible contamination from clay, grit or other extraneous adulterants or impurities.

3. All the other words and expressions used in the regulations not defined above shall have the meanings assigned to them in the Act, Rules, or Regulations thereunder.

4. Scope:- This regulation shall be applicable to all foods to which essential nutrients are added with the intention of fortifying these foods with nutrients, not including vitamin and mineral food supplements. This is applicable, as appropriate to both voluntary and mandatory addition of essential nutrients.

5. Application of other Acts, Regulations and Standards:- The provisions of this regulation shall be applicable to all fortified foods, whether voluntarily fortified or required to undergo mandatory fortification that is manufactured, packed, labeled, handled, stored, distributed, and sold. In the absence of a standard or specifications by national authorities, relevant standards and specifications provided in Codex or World Health Organization (WHO) shall be applicable.

6. General Principles of Fortification:-

(1) Essential nutrients shall be appropriately added to foods as per the conditions stated in Schedule 1 and/or Schedule 2 for delivering any one of the following:

- (a) Preventing/reducing the risk of, or improving, a demonstrated deficiency of one or more essential nutrients in the population.
- (b) Reducing the risk of, or improving, inadequate nutritional status or intakes of one or more essential nutrients in the population.
- (c) Meeting requirements and/or recommended intakes of one or more essential nutrients.
- (d) Maintaining or improving normal health conditions; and/or
- (e) Maintaining or improving the nutritional quality of foods.

(2) Authority from time to time may determine and select foods for fortification for either mandatory or voluntary fortification keeping in view the following considerations through scientific assessments, laboratory testing and deliberations with Nutrition expert committees, as per the Nutrition and Health priorities set by the Government of Bangladesh:

- (a) The addition of an essential nutrient, including the amount specified for addition shall be in line with one or more principles stated in the General Principles above 6.1. The amount added shall not result in either an excessive intake or an insignificant intake of the added essential nutrient(s), considering total daily intakes of the respective nutrient(s) from all food sources including the dietary supplements.
- (b) The maximum amount of nutrient specified to be added in a particular food matrix shall be based on upper levels of safe intake of essential nutrients established by generally accepted scientific data and Recommended daily intake of essential nutrients from all sources of the diet. Considerations to be given to the recommended daily intake values of the essential nutrients for the population and their food habits.
- (c) The minimum amount specified to be added in a particular food matrix shall be based on the assessment that this amount is significant and in line with the purpose of the addition of the nutrient.



(d) The selection of foods to which essential nutrients are specified to be added shall be in line with the intended purposes of nutrient addition as identified in General Principle 6.1, dietary patterns, socioeconomic situations, and the need to avoid any risks to health or long-term adverse effects.

(e) Unless otherwise stated, food fortification as per the requirements of this regulation shall only be allowed in the foods specified in Schedule 1 and Schedule 2.

7. Technological aspects:-

- (1) The sources of the Fortificant may be either natural or synthetic and their selection shall be based on considerations such as safety, purity and bioavailability of the nutrient. In addition, purity criteria shall be in line with the criteria specified by national standards. In the absence of a national standard, standards specified by Codex/WHO or other recognized international standards shall be applicable.
- (2) The added essential nutrient shall be sufficiently stable in the food under customary conditions of processing, packaging, storage, distribution, and use.

8. Monitoring of the food fortification program:-

- (1) Authority from time-to-time monitor population intakes of these specific nutrients from all sources including the essential nutrients added to foods to assess the extent to which the objective of nutrient addition as laid down in the General principles 6.1 are addressed and to ensure that any risk associated with the excessive intake is minimized.
- (2) Monitoring of total Daily Nutrient Intakes shall in principle use the same approach as used in deciding the addition of essential nutrients unless otherwise necessary for the specific nutrient concerned.
- (3) Authority may inspect whether the food item fortified with essential nutrients by the food business operators engaged in refining, fortifying, importing, and selling the fortified food are following the requirements as stated under these regulations.
- (4) Authority shall conduct sampling and analysis of the fortified food or the Fortificant used in fortification and test the level of enrichment thereof from an accredited and/or designated laboratory.

9. Packaging and Labelling requirements:-

- (1) For all kinds of fortified food, , general labeling requirements according to the Food Safety (Labelling of Packaged Food) Regulation, 2017(latest version) shall be applicable.
- (2) Further, the following labeling requirements shall be followed for products under this category:
 - (a) Every package of fortified food shall declare "Fortified with ----- (name of the Fortificant) and amount of Fortificant per 100g". It shall also carry fortification logo as specified in the schedule of this regulation.



(b) Additional information like, the unsuitability of fortified food for any specific person, anti-nutritional activity, and allergic reaction (if any) shall be declared on the label. As an example, fortified food with iron shall carry a declaration 'Not recommended for people with Thalassemia, Sickle Cell Anemia and people on a low iron diet'.

(3) All fortified foods shall be packed in a manner that takes into consideration the nature of the fortificant added and their effect on the shelf life of the food i.e. storage temperature, light, moisture content, etc.

(4) All manufacturers and packers of fortified food complying with their requirements under these Regulations or any other applicable Act, Rules or Regulations shall be permitted to make a nutrition claim in relation to a specific fortified food as per Food Safety (Advertising and Claims) regulation, 2023(latest version) of the Authority.

(5) All other provisions under Food Safety (Food Contact Material) Regulation, 2019(latest version) shall also apply to fortified foods.

10. The manufacturing process shall comply with the Food Safety (Food Hygiene) Regulations, 2018(latest version).

11. Fortified Food and the Fortificant shall comply with the Food Safety (Contaminants, Toxins, and Residues) Regulations, 2017(latest version).

12. Compliance of micronutrient content in Fortified foods:-

(1) The level of micronutrient compliance of fortified food shall be within the range specified in Schedule 1 and/or Schedule 2.

(2) A decrease by ten percent of the declared value of the nutrient on the label of such foods shall be allowed or any other acceptable range declared in any other Act, rules/regulations for the purpose of compliance and analysis at any point of time. Provided that the maximum limits of the added micronutrients in Schedule 1 and/or Schedule 2 shall be complied with.

13. Registration and Statutory actions:-

(1) Food Business Operators who are engaged in fortified food production, processing, storage, supply, import, export, marketing or sale shall be registered and certified for the said activity under the provisions of this regulation of the authority.

(2) Every application for registration under subsection (1) is to be submitted to the authority in such manner as prescribed and payment of such fees as may be prescribed by the authority.

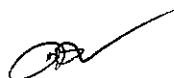
(3) Registration certificate shall be valid for 3(three) years from the date of issuance thereof, and shall, on payment of prescribed fees, be renewable for such period upon fulfillment of necessary conditions.

14. Suspension and Cancellation of Registration, etc:-

- (1) If any provision of these regulations is contravened or any condition specified in a registration certificate is not complied with or any false or untrue information/documents is furnished for registration, the authority may pass an order to suspend or as the case may be, cancel the registration certificate.
- (2) No registration certificate shall be suspended or as the case may be canceled under sub-section (1) without giving the recipient of such registration certificate an opportunity of 15 (fifteen) days' notice to show cause.
- (3) Any person if aggrieved by an order passed under sub-section (1) may file an appeal to the appellate authority within 30 (thirty) days from the date of receipt of such order.
- (4) Chairman of the Bangladesh food safety authority shall act as the appellate officer.
- (5) Within 60 (sixty) days from the date of filing of an appeal under sub-section 3 decision in this regard is to be made, and such decision of the authority shall be final.

15. Publication of English translation:-

- (1) After the commencement of this Regulation, the Authority, with prior approval of the Government, if necessary, by notification in the official Gazette, may publish an Authentic English text of the Regulation.
- (2) Provided that, in the event of a conflict between the Bangla and the English text, the Bangla text shall prevail.



SCHEDULE 1

STANDARDS FOR MANDATORY FORTIFICATION OF STAPLE FOODS

1. Iodized Salt

S.N	Nutrient	Nutrient Level		Source of Nutrient
		Refined Iodized Salt/Vacuum Evaporated Iodized Salt	Traditional Mechanical Iodized Salt	
1.	Iodine a) Manufacture level b) Distribution channel at retail level	a) 30-50 ppm b) 20-50 ppm	a) 30-50 ppm b) 20-50 ppm	(a) Potassium iodide (b) Potassium iodate (c) Sodium iodide (d) Sodium iodate

2. Fortified edible oil (Only Soybean, Palm, Palm Olein, and Palm Stearin)

SL. No.	Nutrient	Level of nutrient	Source of Nutrient
1.	Vitamin A	15-30 ppm	Retinol palmitate or Retinol acetate.

Note 1: ppm means parts per million which is equal to mg of the nutrient added in 1 kg of the specific food.

SCHEDULE 2

STANDARDS FOR VOLUNTARY FORTIFICATION OF FOODS

1. Iron Fortified Iodized Salt (Double Fortified Salt) - Salt shall be fortified with iodine as per table 1, Schedule 1, may also be fortified with iron in combination with iodine as per the table 1 given below:

Double Fortified salt

S.No.	Nutrient	Level of nutrient	Source of Nutrients
1.	Iron content (as Fe)	850-1100 ppm	Ferrous Sulphate or Ferrous Fumarate

Double Fortified Salt may contain hydroxypropyl methyl cellulose, titanium dioxide full hydrogenated soyabean oil and sodium hexametaphosphate (all food grade) and anticaking agent not exceeding 2.0 percent on dry weight basis and the water insoluble matter when anticaking agent is used shall not exceed 2.2 percent.

2. Fortified Rice

S. No	Nutrients-units	Rice consumption of 150-300 g/cap/d, in ppm (mg/kg)	Targeted amount in 100g uncooked rice	Target fortification level, including 30% overage for vitamins to compensate	Target range ex-factory	Expected range at household level
1	Vitamin A (Palmitate)	1.5	150 mcg(=RE)	195 mcg	185-215 mcg	150-215 mcg
2	Vitamin B ₁ (as Thiamin mononitrate)	4	0.4 mg	0.52 mg	0.45-0.60 mg	0.40-0.60 mg
3	Vitamin B ₁₂ (Cyanocobalamine)	0.01	1mcg	1.3 mcg	1.15-1.45 mcg	1.00-1.45 mcg
4	Folic acid (Vitamin B ₉)	1.3	130 mcg	170 mcg	150-190 mcg	130-190 mcg
5	Iron (Ferric pyrophosphate)	60	6 mg	6 mg	5-7 mg	5-7 mg
6	Zinc (as Zinc oxide)	40	4 mg	4 mg	3.5-4.5 mg	3.5-4.5 mg

3 (a). Fortified Milk (Liquid)

S.No.	Nutrient/ Source	Level of nutrient per liter(µg/L)
1	Vitamin A (µg RE)- Retinyl acetate or Retinyl palmitate	270 – 450
2	Vitamin D (µg) *Cholecalciferol or*Ergocalciferol (*Only from Plant source)	5-7.5

Vitamin A (retinol): 1 IU= 0.3 µg RE (Retinol Equivalent); Vitamin D (Cholecalciferol or Ergocalciferol): 1 IU= 0.025 µg

3 (b). Fortified Milk (Powder)

- (i) Milk powder, when fortified, shall be fortified with such levels of Vitamin A and D, so that the final reconstituted fortified milk shall comply with the levels of micronutrients specified in table 3, Schedule 2 related to Fortified Milk when constituted as per the directions mentioned on the product label.
- (ii) It shall only be used in the Government Funded Programs for the purpose of preparation of "Reconstituted Fortified Milk".
- (iii) In addition to the labelling provisions mentioned under Food Safety Act, Rules or Regulations, the label of Fortified Milk Powder shall also carry the following statement:
 - (a) Not recommended for direct consumption.
 - (b) Only for use under -----(name of the government funded program)
 - (c) To be consumed only after reconstitution of the entire content as per the directions on the label.
 - (d) Pack once opened, to be consumed on the same day

3. Fortified Wheat Flour (Atta)

Atta, when fortified, shall contain added iron, folic acid and Vitamin B₁₂ at the level given in the table below:

S.No.	Nutrient/ Source	Level of nutrient per Kg
1	Iron: Ferrous citrate or Ferrous lactate or Ferrous sulphate or Ferric pyrophosphate or electrolytic iron or Ferrous fumarate or Ferrous BisGlycinate;	28 mg -42.5 mg*
	or Sodium Iron (III) Ethylene diamine tetra Acetate Trihydrate (Sodium feredetate-Na Fe EDTA)	14 mg- 21.25 mg
2	Folic acid	75 µg- 125 µg
3	Vitamin B ₁₂ - Cyanocobalamine or Hydroxycobalamine;	0.75 µg- 1.25 µg

Note: * added at a higher level to account for less bioavailability

In addition, atta may also be fortified with following micronutrients, singly or in combination, at the level in the table below:

S.No.	Nutrient/ Source	Level of nutrient per Kg
1	Zinc- Zinc Sulphate;	10 mg- 15 mg
2	Vitamin A- Retinyl acetate or Retinyl Palmitate;	500 µg RE- 750 µg RE
3	Thiamine (Vitamin B ₁)- Thiamine hydrochloride or Thiamine mononitrate;	1 mg- 1.5 mg
4	Riboflavin (Vitamin B ₂)- Riboflavin or Riboflavin 5'-phosphate sodium ;	1.25 mg- 1.75 mg
5	Niacin (Vitamin B ₃) -Nicotinamide or Nicotinic acid;	12.5 mg- 20 mg
6	Pyridoxine (Vitamin B ₆)- Pyridoxine hydrochloride;	1.5 mg- 2.5 mg

Multi-grain Atta may also be fortified with vitamins and minerals at the same levels specified for 'Fortified Atta', provided that the multigrain atta contains more than 50% as wheat flour in it.

5. Fortified wheat flour (Moida)

Moida, when fortified, shall contain added iron, folic acid and Vitamin B-12 at the level given in the table below:

S.No.	Nutrient/ Source	Level of nutrient per Kg
1	Iron: Ferrous citrate or Ferrous lactate or Ferrous sulphate or Ferric pyrophosphate or electrolytic iron or Ferrous fumarate or Ferrous BisGlycinate;	28 mg -42.5 mg*
	or Sodium Iron (III) Ethylene diamine tetra Acetate Trihydrate (Sodium feredetate-Na Fe EDTA)	14 mg- 21.25 mg
2	Folic acid	75 µg- 125 µg
3	Vitamin B ₁₂ - Cyanocobalamin or Hydroxocobalamin;	0.75 µg- 1.25 µg

Note: *added at a higher level to account for less bioavailability

In addition, Maida may also be fortified with following micronutrients, singly or in combination, at the level given in the table below:

S.No.	Nutrient/ Source	Level of nutrient per Kg
1	Zinc- Zinc Sulphate;	10 mg- 15 mg
2	Vitamin A- Retinyl acetate or Retinyl Palmitate;	500 µg RE- 750 µg RE
3	Thiamine (Vitamin B ₁)- Thiamine hydrochloride or Thiamine mononitrate;	1 mg- 1.5 mg
4	Riboflavin (Vitamin B ₂)- Riboflavin or Riboflavin 5'- phosphate sodium ;	1.25 mg- 1.75 mg
5	Niacin (Vitamin B ₃) -Nicotinamide or Nicotinic acid;	12.5 mg- 20 mg
6	Pyridoxine (Vitamin B ₆)- Pyridoxine hydrochloride;	1.5 mg- 2.5 mg

By order of the Bangladesh Food Safety Authority

Md. Abdul Kayowm Sarker

Chairman (Additional Secretary)