

Food Safety and Standards (Fortification of Foods) Regulations, 2018

PART 1: GENERAL

1. Short title and commencement. - (1) These regulations may be called the Food Safety and Standards (Fortification of Foods) Regulations, 2018.

(2) They shall come into force on the date of their publication in the Official Gazette and Food Business Operator shall comply with all the provisions of these regulations by 1st January, 2019.

(3) The provisions of these regulations shall supersede standards on fortification of food set out in any regulations, orders, or guidelines issued under the Act thereunder save as regards regulations on nutraceuticals and foods for Special Dietary Uses.

2. Definitions. – (1) In these regulations, unless the context otherwise requires: -

(a) “**Act**” means the Food Safety and Standards Act, 2006 (34 of 2006);

(b) “**fortification**” means deliberately increasing the content of essential micronutrients in a food so as to improve the nutritional quality of food and to provide public health benefit with minimal risk to health;

(c) “**fortificant**” means a substance added to food to provide micronutrients but does not include nutraceuticals or foods for Special Dietary Uses;

(d) “**fortified food**” means a food, as specified under the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, that has undergone the process of fortification as per the provisions of these regulations;

¹[(da) “**Fortified Processed Foods**” means processed foods (i.e., foods that have been altered from its natural state by industrial processing methods) that have undergone the process of fortification as per the provisions of these regulations. The same may have fortified staples as raw materials and/or fortified with permitted micronutrients and additives as specified under the Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011.]

(e) “**Government-funded programme**” means any programme, policy, scheme or other provision under which food is sold, distributed or otherwise made available to the public by the Central or State Governments;

(f) “**micronutrients**” means essential dietary nutrients including vitamins, minerals or trace elements that are required in very small quantities and are vital to development, disease prevention and wellbeing of human beings;

(g) “**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;

(h) “**staple foods**” means articles of food intended for mass consumption on a daily basis and include rice, wheat, wheat flour, *atta*, *maida*, oil, salt, milk, and such other articles of food as may be designated staple foods under these regulations;

(2) All other words and expressions used and, not defined in these regulations shall have the meanings assigned to them in the Act, rules or regulations made thereunder.

PART 2: STANDARDS ON FORTIFICATION

3. General principles.-(1) Micronutrients may be appropriately added to foods for the purpose of contributing to any of the following as mentioned in Schedule-I:

- (a) Preventing or reducing the risk of, or correcting, a demonstrated deficiency of one or more micronutrients in the population or specific population group;
 - (b) reducing the risk of, or correcting, inadequate nutritional status of one or more micronutrients in the population or specific population group;
 - (c) meeting requirements or recommended intake of one or more micronutrients;
 - (d) maintaining or improving health;
 - (e) maintaining or improving the nutritional quality of foods.
- (2) When fortification of a food is made mandatory, it shall be based on severity and extent of public health need as demonstrated by generally accepted scientific evidence.
- (3) The Food Authority may, specify mandatory fortification of any staple food on direction of the Government of India.
- (4) Wherever “Iron (As Fe)” is used as a source of nutrient, heme iron shall not be used in any form in any article of food.
- (5) ¹[Fortified Processed Foods may be prepared from fortified food articles that may be cereals and/or milk;
- (6) The Fortified Processed Food shall provide 15-30% of the Indian adult RDA of micronutrient based on an average calorie intake of 600 kcal from processed foods (approximately 1/3rd of daily energy requirement for an adult);
- (7) High Fat Sugar Salt (HFSS) Foods shall be excluded from Fortified Processed Foods category. The definition of HFSS foods shall have the same meaning as specified under the Food Safety and Standards (Labelling and Display) Regulations, 2020.]

4. Compliance with Standards on Micronutrient Content in Fortified Food.-

(1) Any manufacturer who fortifies any food shall ensure that the level of micronutrient in such fortified food does not fall below the minimum level specified in Schedule- I.

Amendment for substitution of highlighted provision

³[Any manufacturer who fortifies any food shall ensure that the level of added micronutrients on label of such fortified food shall fall within the range specified in Schedule-I.

The tolerance of minus 10 percent of the declared total value on the label may be allowed for the purposes of compliance and analysis at any point in time. Provided that the maximum limit of added micronutrients specified in Schedule-I must be complied with.]

[Amendment in force from 22nd September, 2021; FBOs to comply with the provisions by 1st April, 2022]

¹[(2) Any manufacturer who fortifies any processed food shall ensure that the level of micronutrients in such fortified processed food shall fall within the range specified in Schedule-III.]

PART 3: GENERAL OBLIGATIONS

5. Quality Assurance.- (1) Every manufacturer and packer of fortified food shall give an undertaking on quality assurance and submit evidence of steps taken in this regard to the Food Authority or such other authority which the Food Authority may designate.

(2) The undertaking shall be given twice a year and shall include, the following, namely:-

- (a) certification by a food laboratory notified by the Food Authority that the fortified food is in compliance with the provisions of the Act and regulations and standards specified therein;
- (b) up-to-date record keeping and continuous inventory of fortificants used in the manufacturing or packing process, including the source of its procurement;
- (c) appropriate monitoring procedures at different stages of manufacturing or packing process;
- (d) random testing of fortificants and fortified food;
- (e) regular audit of technical equipment and processes;
- (f) such good manufacturing practices, as may be specified by the Food Authority from time to time.
- (g) provisions for the reference of the purity criteria of micronutrients, generally accepted by pharmacopoeias, namely, Indian Pharmacopoeia, British Pharmacopoeia, Food Chemical Codex, Joint Food and Agriculture Organization or World Health Organisation Expert Committee on Food Additives or CODEX Alimentarius may be adopted by food Business operators.

6. Compliance with the generally applicable provisions of the Act, Regulations and Standards.- All fortified food, whether voluntarily fortified or required to undergo mandatory fortification shall be manufactured, packed, labeled, handled, distributed and sold, whether for profit or under a Government-

funded programme, only in compliance with the standards specified under the provisions of the Act and regulations made thereunder.

7. Packaging and Labeling Requirements. – (1) 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.

(2) Every package of fortified food shall carry the words “fortified with (name of the fortificant)” and the logo, specified in Schedule-II of these regulation, on its label. It may also carry a tag line “Sampoorna Poshan Swasth Jeevan” under the logo.

¹[Provided that the requirements as specified in sub-regulation (2) is not required in case of iodized salt (when fortified with iodine).]

(3) provisions of the Food Safety and Standards (Packaging and Labeling) Regulations, 2011, shall also apply to the fortified foods.

(4) Every package of food, fortified with Iron shall carry a statement “*People with Thalassemia may take under medical supervision*”.

Amendment for substitution of highlighted provision

²[(4) Every package of food, fortified with Iron shall carry a statement “*People with Thalassemia may take under medical supervision and persons with Sickle Cell Anaemia are advised not to consume iron fortified food products.*”]

[Amendment in force from 27th August, 2021; FBOs to comply with the provisions by 1st March, 2022]

(5) All manufacturers and packers of fortified food complying with the provisions of the Act and rules or regulations made thereunder on fortified food shall be permitted to make a nutrition claim in relation to an article of fortified food under the Food Safety and Standards (Packaging and Labeling) Regulations, 2011.

8. Promotion of Fortified Food. - (1) The Food Authority shall take steps to encourage the production, manufacture, distribution, sale and consumption of fortified food including fortification through conventional breeding or hybridization, in cooperation with concerned departments of the Government of India/Government of States/UTs.

(2) Without prejudice to the generality of sub-regulation (1), the Food Authority shall endeavor to:

- (a) advise and promote the use of fortified food in Government-funded programmes on distribution of food;
- (b) organise public awareness, educate and advocate campaigns on nutrition and fortified food;

(c) conduct technical assistance programmes and provide technical expertise to small manufacturers to enable them to undertake fortification;

(d) equip laboratories and research institutions notified under the Act to conduct the nutrient analysis of fortified food |

SCHEDULE-I

STANDARDS FOR FORTIFICATION OF FOODS

[See sub-regulation (1) of regulation 4]

1. 1) Iodized salt (when fortified with Iodine)

2) Iron fortified iodized Salt (Double Fortified Salt) when fortified with Iron and Iodine Salt shall be fortified with Iodine¹ and may also be fortified with iron in combination² with iodine, at the level given in the table below:

Sl.No.	Component	Level of nutrients	Source of nutrients
1.	Iodine content		
	(a) Manufacture level	20-30 parts per million (on dry weight basis)	Potassium Iodate
	(b) Distribution channel including retail level	15-30 parts per million (on dry weight basis)	
Amendment for substitution of highlighted provision			
² [1.	Iodine content	15-30 part per million (on dry weight basis.	Potassium Iodate]
<i>[Amendment in force from 27th August, 2021; FBOs to comply with the provisions by 1st March, 2022]</i>			
2.	Iron content (as Fe)	850-1100 parts per million	Ferrous sulphate or Ferrous Fumarate

¹The total matter insoluble in water where an anticaking agent has been added shall not exceed 2.2 per cent. and Sodium Chloride content on dry basis shall not be less than 97.0 per cent. by weight and it shall also conform other parameter as mentioned under clause (1) of sub-regulation 2.9.30 of the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011.

²Double fortified salt may contain Hydroxypropyl Methyl Cellulose, Titanium dioxide full Hydrogenated Soybean oil and Sodium Hexametaphosphate (all food grade) and anticaking agent not more than 2.0 per cent. On dry weight basis and the water insoluble matter wherein anticaking agent is used shall not exceed 2.2 per cent.

2. Fortified Oil: Vegetable Oil, when fortified, shall be fortified with the following micronutrients, at the level given in the table below:

Sl. No.	Nutrient	Level of nutrient	Source of nutrient
1.	Vitamin A	6 µg RE - 9.9 µg RE per gm of oil	Retinyl acetate or Retinyl palmitate
2.	Vitamin D	0.11 µg– 0.16 µg per gm of oil.	*Cholecalciferol or *Ergocalciferol (*Only from Plant Source)

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

¹[3. Fortified Milk

Species identified milk (namely buffalo milk, cow milk, goat milk, sheep milk and camel milk), full cream milk, toned milk, double toned milk, skimmed milk and standardized milk, when fortified, shall be fortified with the following micronutrients at the level given in the table below, wherein the milk is to undergo the process of pasteurization, sterilization, ultra high temperature sterilization/treatment or boiling:

S. No.	Nutrients/Source	Level of nutrient per litre of Species identified milk (namely buffalo milk, cow milk, goat milk, sheep milk and camel milk)/full cream milk/toned milk/double toned milk/skimmed milk/standardized milk
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

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

Amendment for insertion of new provision

²[3A. 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 Clause 3 of Schedule-I 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 and Standards 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 Programme);

(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.]

[Amendment in force from 27th August, 2021; FBOs to comply with the provisions by 1st March, 2022]

4. Fortified Atta

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

Sl.No.	Nutrient	Level of fortification 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 B12- 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:

Sl.No.	Nutrient	Level of fortification per Kg
1.	Zinc- Zinc Sulphate;	10 mg- 15 mg
2.	Vitamin A- Retinyl acetate or RetinylPalmitate;	500 µg RE- 750 µg RE
3.	Thiamine (Vitamin B1)- Thiamine hydrochloride or	1 mg- 1.5 mg

	Thiamine mononitrate;	
4.	Riboflavin (Vitamin B2) - Riboflavin or Riboflavin 5'-phosphate sodium ;	1.25 mg- 1.75 mg
5.	Niacin(Vitamin B3) -Nicotinamide or Nicotinic acid;	12.5 mg- 20 mg
6.	Pyridoxine(Vitamin B6) - Pyridoxine hydrochloride;	1.5 mg- 2.5 mg

¹[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 Maida

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

Sl.No.	Nutrient	Level of fortification per Kg
1.	Iron- (a) 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 (b) 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 B12- Cyanocobalamine or Hydroxycobalamine;	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:

Sl.No.	Nutrient	Level of fortification 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 B1) - Thiamine hydrochloride or Thiamine mononitrate;	1 mg- 1.5 mg

4.	Riboflavin (Vitamin B2) - Riboflavin or Riboflavin 5'-phosphate sodium ;	1.25 mg- 1.75 mg
5.	Niacin(Vitamin B3) -Nicotinamide or Nicotinic acid;	12.5 mg- 20 mg
6.	Pyridoxine(Vitamin B6) -Pyridoxine hydrochloride;	1.5 mg- 2.5 mg

6. Fortified Raw Rice

Amendment for substitution of highlighted provision

²[6. Fortified Rice]

[Amendment in force from 27th August, 2021; FBOs to comply with the provisions by 1st March, 2022]

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

Sl.No.	Nutrient	Level of fortification per Kg
1.	Iron- (a) Ferric pyrophosphate	28 mg- 42.5 mg *
	Or (b) Sodium Iron (III) Ethylene diamine tetra Acetate Trihydrate (Sodium ferredetate -Na Fe EDTA);	14 mg- 21.25 mg
2.	Folic acid -Folic acid;	75 µg- 125 µg
3.	Vitamin B12- Cyanocobalamine or Hydroxycobalamine;	0.75 µg- 1.25 µg

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

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

Sl.No.	Nutrient	Level of fortification per Kg
1.	Zinc -Zinc Oxide;	10 mg- 15 mg
2.	Vitamin A - Retinyl Palmitate;	500 µg RE- 750 µg RE
3.	Thiamine (Vitamin B1) - Thiamine hydrochloride or Thiamine mononitrate;	1 mg- 1.5 mg
4.	Riboflavin (Vitamin B2) - Riboflavin or Riboflavin 5'-phosphate sodium;	1.25 mg- 1.75 mg
5.	Niacin (Vitamin B3) - Nicotinamide or Nicotinic acid;	12.5 mg- 20 mg
6.	Pyridoxine (Vitamin B6) - Pyridoxine hydrochloride;	1.5 mg- 2.5 mg

SCHEDULE-II

[See sub-regulation (2) of regulation 7]



Fortified with....

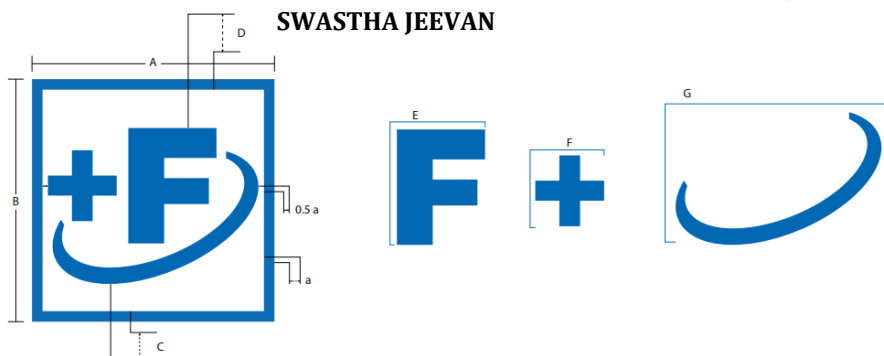
SAMPOORNA POSHAN

SWASTHA JEEVAN



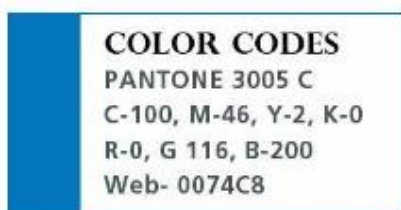
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सम्पूर्ण पोषण स्वस्थ जीवन



All dimensions in millimeters

A	B	C	D	a	E (w x h)	F (w x h)	G (w x h)
20	20	2.2	3.1	0.8	7.27 x 9.51	5.67 x 5.84	16.98 x 10.93
40	40	4.4	6.3	1.7	14.54 x 19.03	11.35 x 11.68	33.96 x 21.87
80	80	8.9	12.5	3.4	29.08 x 38.07	22.7 x 23.36	67.92 x 43.75
160	160	17.9	25.4	6.9	58.17 x 76.14	45.39 x 46.72	135.85 x 87.5
320	320	35.6	50.6	13.8	116.35 x 152.29	90.77 x 93.44	275.25 x 175.01



¹[SCHEDULE-III

STANDARDS FOR FORTIFIED PROCESSED FOODS

[See sub-regulation (2) of regulation 4]

1. Fortified Cereal Products:

(1) Cereal products include Breakfast cereals, Pasta and Noodles, when fortified, shall contain added iron, folic acid and Vitamin B₁₂ at the level given in the table below, namely:-

Table

S. No.	Nutrients/Source	Level of nutrient per 100 g
1	Iron (mg) Ferrous citrate or Ferrous lactate or Ferrous sulphate or Ferric pyrophosphate or electrolytic iron or Ferrous fumarate or Ferrous bis glycinate; or Sodium Iron (III) Ethylene diamine tetra acetate, trihydrate (Sodium ferredetate -Na Fe EDTA);	1.4-2.7
2	Folic acid (µg)	8-16
3	Vitamin B₁₂ (µg) - Cyanocobalamine, or Hydroxycobalamine	0.08-0.16

(2) In addition, fortified cereal products, when fortified, may also be fortified with following micronutrients, singly or in combination, at the level in the table below, namely:-

Table

S. No.	Nutrients/Source	Level of nutrient per 100 g
1.	Zinc (mg): Zinc Sulphate	1.0-1.9
2.	Vitamin A (µg RE): Retinyl acetate or Retinyl Palmitate,	48-96
3.	Thiamine (Vitamin B₁) (mg): Thiamine hydrochloride or Thiamine mononitrate;	0.1-0.19
4.	Riboflavin (Vitamin B₂) (mg): Riboflavin or Riboflavin 5'-phosphate sodium ;	0.11-0.22
5.	Niacin(Vitamin B₃) (mg): Nicotinamide or Nicotinic acid;	1.3-2.6
6.	Pyridoxine (Vitamin B₆) (mg): Pyridoxine hydrochloride;	0.2-0.3

2. Fortified bakery wares:

(1) Bakery wares includes bread, biscuits, rusks and buns ,when fortified, shall contain added iron, folic acid and Vitamin B₁₂ at the level given in the table below, namely:-

Table

S. No.	Nutrients/Source	Level of nutrient per 100 g
1	Iron (mg): Ferrous citrate or Ferrous lactate or Ferrous sulphate or Ferric pyrophosphate or electrolytic iron or Ferrous fumarate or Ferrous bisglycinate; or Sodium Iron (III) Ethylene diamine tetra acetate, trihydrate (Sodium ferredetate -Na Fe EDTA);	1.4-2.7
2	Folic acid (µg)	8-16
3	Vitamin B₁₂ (µg)- Cyanocobalamine, or Hydroxycobalamine;	0.08-0.16

(2) In addition, fortified bakery wares, when fortified may also be fortified with following micronutrients, singly or in combination, at the level in the table below:

Table

S. No.	Nutrients/Source	Level of nutrient per 100 g
1.	Zinc (mg): Zinc Sulphate	1.0-1.9
2.	Vitamin A (µg RE): Retinyl acetate or Retinyl Palmitate,	48-96
3.	Thiamine (Vitamin B₁) (mg): Thiamine hydrochloride or Thiamine mononitrate;	0.1-0.19
4.	Riboflavin (Vitamin B₂) (mg): Riboflavin or Riboflavin 5'-phosphate sodium ;	0.11-0.22
5.	Niacin(Vitamin B₃) (mg): Nicotinamide or Nicotinic acid;	1.3-2.6
6.	Pyridoxine (Vitamin B₆) (mg): Pyridoxine hydrochloride;	0.2-0.3

3. Fortified Fruit Juices:

(1) Fruit juices, when fortified, shall contain Vitamin C at the level given in the table below:

Table

S. No.	Nutrients/Source	Level of nutrient per 100 m L
1.	Vitamin C (mg): Ascorbic acid	6-12]

Note. - The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 *vide* notification number File No. 11/03/Reg/Fortification/2014, dated the 2st August, 2018 and subsequently amended *vide* notification no.:

1. F. No. REG/Fortification Amendment (1)/Notification/FSSAI-2018, dated 18th December, 2020.
2. F. No. Stds/SP-18/A-1.12/N-1, dated 27th August, 2021.
3. F. No. 1-116/Scientific Committee/Notif.28.6/2010-FSSAI, dated 22nd September, 2021.