

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

UNION OF INDIA

India

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

Rule

THE-FOOD-SAFETY-AND-STANDARDS-FORTIFICATION-OF-FOODS-F of 2018

- Published on 2 August 2018
- Commenced on 2 August 2018
- [This is the version of this document from 2 August 2018.]
- [Note: The original publication document is not available and this content could not be verified.]

The Food Safety and Standards (Fortification of Foods) Regulations, 2018Published vide Notification No. F. No. 11/03/Reg/Fortification/2014, dated 2nd August, 2018Ministry of Health and Family Welfare(Food Safety and Standards Authority of India)F. No. 11/03/Reg/Fortification/2014. - Whereas the Food Safety and Standards (Fortification of Foods) Regulations, 2016 were published as required under sub section (1) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), vide notification No. 11/03/Reg/Fortification/2014, dated the 23rd December, 2016, in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of thirty days from the date on which the copies of the Gazette containing the said notification were made available to the public;And whereas copies of the said Gazette were made available to the public on the 3rd January, 2017;And whereas objections and suggestions received from the public in respect of the said draft regulations have been considered by the Food Safety and Standards Authority of India;Now, therefore, in exercise of the powers conferred by clause (e) of sub- section (2) of section 92 of the said Act, the Food Safety and Standards Authority of India hereby makes the following regulations, namely:-

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; (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.

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.

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. (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". (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; and

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(b) Distribution channel including retail level	20-30 parts permillion (on dry weight basis)15-30 parts per million (on dry weight basis)	Potassium Iodate	
2.	Iron content (as Fe)	850-1100 parts per million	Ferrous sulphate or Ferrous Fumarate

1. The 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.

2. Double 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 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

3. Fortified Milk Toned, double toned, skimmed milk or standardized milk shall be fortified with the following micronutrients, at the level given in the table below:

Sl. No.	Nutrient	Level of nutrient per litre of toned/doubletoned/skimmed milk/standardized	Source of nutrient
1.	Vitamin A	270 µg RE - 450 µg RE	Retinyl acetate or Retinyl palmitate
2.	Vitamin D	5 µg– 7.5 µg	*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

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 Ferroussulphate or Ferric pyrophosphate or	28 mg- 42.5 mg*

	electrolytic iron or Ferrous fumarate or Ferrous BisGlycinate;	
	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 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

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);	
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, 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 tetraacetate 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)- Pyridoxinehydrochloride; 1.5 mg- 2.5 mg
II

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