

File No. 11/03/Reg/Fortification/2014 (pt. III)

Food Safety and Standards Authority of India

(A statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)

FDA Bhawan, Kotla Road, New Delhi-110002

The 16th May, 2018

Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding Operationalisation of Food Safety and Standards (Fortification of Foods) Regulations, 2018 relating to standards for fortification of food.

In exercise of the powers conferred under Section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), the FSSAI has framed the Food Safety and Standards (Fortification of Foods) Regulations, 2016.

2. The draft regulations were notified in the Gazette of India vide File No. 11/03/Reg/Fortification/2014 dated 23.12.2016 inviting comments and suggestions from the stakeholders. The draft regulations were operationalised up to 18.04.2018 in exercise of the power vested in the Food Authority under section 18 (2) (d) read with section 16 (5) of the Food Safety and Standards Act, 2006. The final regulations have now been approved by Food Authority in its 24th meeting and the same are under process of notification. Since this is likely to take some more time, it has been decided to re-operationalise the Food Safety and Standards (Fortification of Foods) Regulations, enclosed herewith, w.e.f. 19.04.2018.

4. This issues with the approval of the Competent Authority in exercise of the power vested under Sections 18(2) (d) and 16(5) of Food safety and Standards Act, 2006.



(Sunil Bakshi)
Advisor (Regulations)

Enclosure: as above

To

1. All Food Safety Commissioners,
2. All Authorized Officers, FSSAI,
3. All Designated Officers, FSSAI.

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. All Directors, FSSAI

Notice for operationalisation of Food Safety and Standards (Fortification of Foods) Regulations, 2018.

CHAPTER 1: GENERAL

1. Short Title and commencement. - (1) these regulations may be called the Food Safety and Standards (Fortification of Foods) Regulations, 2017

(2) The enforcement of these regulations shall commence only after the final regulations are notified in the Gazette of India.

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

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

(b) “**atta**” means atta as defined in Regulation 2.4.1.1 of the Food Safety and (Food Products Standards and Food Additives) Regulations, 2011;

(c) “**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;

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

(e) “**fortified food**” means food that has undergone the process of fortification as per the provisions of these Regulations;

(f) “**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;

(g) “**international standards**” means the standards and guidelines of the Codex Alimentarius and principles of fortification laid down by the World Health Organization and the Food and Agriculture Organization;

(h) “**maida**” means maida as defined in Regulation 2.4.2.1 of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011;

(i) "**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;

(j) "**milk**" includes milk and its variants as listed under Regulation 1.2. of the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011;

(k) "**nutrition claim**" means any representation which states, suggests or implies that a food has particular nutritional properties which are not limited to the energy value but include protein, fat, carbohydrates, vitamins and minerals;

(l) "**oils**" includes edible oils, vegetable oils, refined edible hydrogenated oils and their variants as listed under Regulation 2.2 of the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011;

(m) "**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;

(n) "**rice**" means rice as defined in Regulation 2.4.6.5 of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011;

(o) "**salt**" means edible common salt as defined in Regulation 2.9.30 of the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011;

(p) "**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;

(q) "**wheat**" means wheat as defined in Regulation 2.4.6.2 of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011;

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

CHAPTER 2: STANDARDS ON FORTIFICATION

3. General principles.- (1) Essential nutrients may be appropriately added to foods for the purpose of contributing to any of the following:

- (a) Preventing or reducing the risk of, or correcting, a demonstrated deficiency of one or more essential nutrients in the population or specific population group;
- (b) reducing the risk of, or correcting, inadequate nutritional status of one or more essential nutrients in the population or specific population group;
- (c) meeting requirements or recommended intake of one or more essential nutrients;
- (d) maintaining or improving health;
- (e) maintaining or improving the nutritional quality of foods.

(1) 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.

(2) The Food Authority may, specify mandatory fortification of any staple food on the directions of the Government of India.

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 the schedule.

(2) Every manufacturer shall ensure that the level of micronutrient in such fortified food does not exceed the highest amount of micronutrient that can safely be added to such food, having regard to recognised international standards.

CHAPTER 3: GENERAL OBLIGATIONS

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

(2) The undertaking on quality assurance shall include, the following, namely:-

- (a) certification by a food laboratory notified by the Food Safety and Standards Authority of India 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 from where the fortificant was procured;
- (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; and
- (f) such good manufacturing practices, as may be specified by the Food Authority from time to time.

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, as specified in the Schedule II of these Regulations, on the label.
- (3) All other provisions under 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 "*Not recommended for people with Thalassemia and people on low iron diet*".

(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 regulation 2.2.2(3) of the Food Safety and Standards (Packaging and Labeling) Regulations, 2011.

8. Promotion of Fortified Food. - (1) With a view to promote wholesome food in the country, the Food Authority shall take steps to encourage the production, manufacture, distribution, sale and consumption of fortified food including fortification through conventional breeding/ hybridization, in cooperation with concerned government departments

(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, education and advocacy 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

(e) identify and recommend to the Central and State Governments, financial incentives, subsidies and loans to be provided to manufacturers and packers to encourage them to undertake fortification.

9. Consolidation of regulations and standards on fortified food. - 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.

10. Provisions of the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 to prevail.

Nothing in these regulations shall affect the provisions of the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 (41 of 1992) or any rules, regulations or orders framed thereunder.

SCHEDULE-I

STANDARDS FOR FORTIFICATION OF FOODS

(See sub-regulation (1) of Regulation 4)

1. Standards for Fortification of Salt with 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:

S.No.	Component	Level of nutrients
1.	Iodine content	
	(a) Manufacture level	Not less than 30 parts per million on dry weight basis
	(b) Distribution channel including retail level	Not less than 15 part per million on dry weight basis.
2.	Iron content (as Fe)	850-1100 parts per million

2. Standards for Fortification of Vegetable Oil with Vitamin A or Vitamin D

Vegetable Oil may be fortified with the following micronutrients, singly or in combination, at the level given in the table below:

S. No.	Nutrient	Minimum level of nutrient	Source of nutrient
1.	Vitamin A	25 IU per gm of oil	Retinyl acetate, Retinyl palmitate and Retinyl propionate
2.	Vitamin D	4.5 IU per gm of oil.	Cholecalciferol, Ergocalciferol

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. As mentioned under sub-regulation 2.9.30.2 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.

3. Standards for Fortification of Milk with Vitamin A or Vitamin D

Standardized, Toned, double toned or skimmed milk may be fortified with the following micronutrients, singly or in combination, at the level given in the table below:

S. No.	Nutrients	Mnimum Level of nutrient per litre of toned/double toned/skimmed milk	Source of nutrient
1.	Vitamin A	770 IU	Retinyl acetate, Retinyl palmitate and Retinyl propionate
2.	Vitamin D	550 IU	Cholecalciferol, Ergocalciferol

4. Standards for Fortification of Vanaspati

Vanaspti shall be fortified with the following micronutrient at the level given in the table below:

S.No.	Nutrient	Level of nutrient
1.	Synthetic Vitamin A	Not less than 25 International Units per gram at the time of packing. Should test positive when tested with Antimony Trichloride (Carr-Price Reagent) as per IS:5886-1970

5. Standards for Fortification of Atta

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

S.No.	Nutrient	Minimum Level of Fortification per Kg
1.	Iron- Sodium Iron (III) Ethylene diamine tetra Acetate, Trihydrate (Sodium fertrate-Na Fe EDTA);	20 mg
2.	Folic acid	1300 µg
3.	Vitamin B12- cyanocobalamine, hydroxycobalamine;	10 µg

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

S.No.	Nutrient	Minimum Level of Fortification per Kg
1.	Zinc-Zinc Sulphate	30 mg
2.	Vitamin A- Retinyl acetate, Retinyl Palmitate, Retinyl Propionate;	1500 µg RE
3.	Thiamine (Vitamin B1)- Thiamine hydrochloride, Thiamine mononitrate;	3.5 mg
4.	Riboflavin (Vitamin B2)- Riboflavin , Riboflavin 5'-phosphate sodium ;	4 mg
5.	Niacin- Nicotinamide, Nicotinic acid;	42 mg
6.	Pyridoxine(Vitamin B6)- Pyridoxine hydrochloride;	5 mg

6. Standards for Fortification of Maida

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

S.No.	Nutrient	Minimum Level of Fortification per Kg
1.	Iron- (a) Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferrous pyrophosphate, electrolytic iron, Ferrous fumarate; (b) Sodium Iron (III) Ethylene diamine tetra Acetate, Trihydrate (Sodium federate-Na Fe EDTA);	60 mg 20 mg
2.	Folic acid	1300 µg
3.	Vitamin B12- cyanocobalamine, hydroxycobalamine;	10 µg

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	Minimum Level of Fortification per Kg
1.	Zinc-Zinc Sulphate	30 mg
2.	Vitamin A- Retinyl acetate, Retinyl Palmitate, Retinyl Propionate;	1500 µg RE
3.	Thiamine (Vitamin B1)- Thiamine hydrochloride, Thiamine mononitrate;	3.5 mg
4.	Riboflavin (Vitamin B2)- Riboflavin , Riboflavin 5'-phosphate sodium ;	4 mg
5.	Niacin- Nicotinamide, Nicotinic acid;	42 mg
6.	Pyridoxine(Vitamin B6)- Pyridoxine hydrochloride;	5 mg

7. Standards for fortification of Rice

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

S.No.	Nutrient	Level of Fortification per Kg
1.	Iron- (a) Ferric pyrophosphate (b) Sodium Iron (III) Ethylene diamine tetra Acetate, Trihydrate (Sodium federate-Na Fe EDTA);	20 mg
2.	Folic acid-Folic acid;	1300 µg
3.	Vitamin B12- cyanocobalamine, hydroxycobalamine;	10 µg

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

S.No.	Nutrient	Level of Fortification per Kg
1.	Zinc-Zinc Oxide	30 mg
2.	Vitamin A- Retinyl Palmitate;	1500 µg RE
3.	Thiamine (Vitamin B1)- Thiamine hydrochloride, Thiamine mononitrate;	3.5 mg
4.	Riboflavin (Vitamin B2)- Riboflavin , Riboflavin 5'-phosphate sodium ;	4 mg
5.	Niacin-Nicotinamide, Nicotinic acid;	42 mg
6.	Pyridoxine(Vitamin B6)-Pyridoxine hydrochloride;	5 mg

SCHEDULE-II

