Notice Calling for suggestions, views, comments etc from WTO- TBT Committee members within a period of 60 days on the draft notification related to standards of Foods for Infant Nutrition.

F. No. Stds/03/Notification (IFR)/ FSSAI-2017.-

1. These regulations may be called as the Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2017.

2. Definitions, -

(1) "Act" means the Food Safety and Standards Act, 2006 (34 of 2006);

(2) "Food Authority" means the Food Safety and Standards Authority of India established under section 4 of the Act;

(3) "Infant" means a person not more than 12 months of age.

(4) "Infant Food" shall have the meaning assigned to it in clause (x) of sub-section (1) of Section 3 of the Act;

(5) "Infant Milk substitute" shall have the meaning assigned to it in clause (x) of sub-section (1) of Section 3 of the Act;

(6) "Infant milk food" means a breast-milk substitute specially manufactured to meet the nutritional requirements of infant.

(7) "Infant formula" means a breast milk substitute specially manufactured product based on milk of cow or buffalo or mixture thereof and other ingredients which have been proven to be suitable for infant feeding, to meet the nutritional requirements of infant.

(8) "Milk cereal based complementary food" means the food based on milk, cereals and /or legumes (pulses), millets, nuts and protein concentrates/protein isolates and/or defatted edible oilseed extracts and so prepared as to permit dilution with water or milk or other suitable medium.

(9) "Processed cereal based complementary food" means food based on cereals and legumes (pulses), millets, nuts and protein isolates/protein concentrates or de-fatted edible oil seed extracts and so prepared as to permit dilution with water milk or other suitable medium.

(10) "Follow-up formula" means a food intended for use as a liquid part of the complementary diet for infants when prepared in accordance with instructions for use.

(11) "Infant Formula for special medical purpose" means a substitute for human milk or infant formula that is specially manufactured to meet the special nutritional requirements of infants with specific disorders, diseases or medical conditions.

(12) "Foods for Infant based on traditional food ingredients" are products known to be prepared traditionally at home for feeding infants, but processed and provided in packaged forms.

(13) "Schedules" means the Schedules to these regulations.

3. General requirements:

(1) Foods for infant nutrition shall be packed in hermetically sealed, clean and sound containers or in flexible pack made from paper, polymer and/ or metallic film as per the Food Safety and Standards (Packaging & Labelling) Regulations, 2011, so as to protect the contents from deterioration. It shall be packed under inert atmosphere.

(2) The category infant formula for special medical purposes provided under these regulations shall be exempted from provisions specified under the Regulation 2.4 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011.

Provided further that if any ingredients with known allergenicity are present, a warning shall be declared on the label.

(3) The categories infant formula for special medical purpose and food for infant based on traditional food ingredients provided under these regulations shall conform to the microbiological standards for milk and milk products of category infant formula as provided under Appendix B of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

(4) A variation of ± 5.0% of the declared values of the added ingredients due to analytical variations shall be allowed.

(5) Wherever applicable, food for infant nutrition shall use the source compounds for minerals, vitamins and other nutrients from Schedule I (a), Schedule I (b) and Schedule I (c), respectively provided under these regulations.

(6) Foods for infant nutrition may contain algal and fungal oil as sources of Docosahexaenoic Acid (DHA) and Arachidonic Acid (ARA) from *Crypthecodinium cohnii, Mortierella alpina, Schizochytrium* sp., and *Ulkenia* sp. at the level of maximum 0.5 per cent. DHA of total fatty acids and ratio of ARA:DHA as 1:1 minimum.

Provided that DHA content shall not be less than 0.2 per cent. of total fatty acids, if a claim related to the addition of DHA is made.

Provided further that Infant Milk substitutes for premature infants shall contain not less than 0.2 % DHA of total fatty acids and ratio of ARA:DHA as 1:1 minimum.

(7) No person shall manufacture, sell, store or exhibit for sale, an infant milk food, infant formula and milk cereal based complementary food, processed cereal

based complementary food and follow up formula except under Bureau of Indian Standards Certification Mark.

Provided that the category infant formula for special medical purpose provided under these regulations shall be exempted from the above provision.

(8) Food for infant nutrition except in the category of food for special medical purpose shall also comply with the requirements of the "Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 as amended in 2003 (IMS Act)".

4. Infant Milk Food:

(1) Scope: This standard applies to infant milk food in powder form for meeting the normal nutritional requirements of infant.

(2) Composition: (i) Infant milk food is a product based on milk of cow or buffalo or mixture thereof, and other nutrients and ingredients which have been provided under these regulations.

(ii) The product may be modified by partial removal or substitution of different milk solids and addition of carbohydrates such as sucrose, dextrose, maltose, lactose and maltodextrin; and salts such as phosphates and citrates.

(iii) The product shall be uniform and free from lumps and coarse particles. It shall be free from rancid taste and musty odour.

(iv) The infant milk food shall conform to the following requirements, namely:

Sl. No.	Parameters	Limits		Limits per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
1.	Moisture, per cent by weight	-	4.5	-	-
2.	Total milk protein (N x 6.38), per cent by weight	12.0	-	2.50	-
3.	Milk fat, per cent by weight	18.0	-	3.80	-
4.	Total ash, per cent by weight	-	8.50	-	-
5.	Ash insoluble in dilute hydrochloric acid, per cent by weight	-	0.10	-	-
6.	Trans fatty acids, per cent by weight of total fatty acids	-	3.0	-	-
7.	Energy per 100 ml of the reconstituted product prepared in accordance with manufacturer's instructions	60 kcal	70 kcal	-	-
8.	Carbohydrates, g per 100 g	45.0	70.0	9.60	14.90
9.	Vitamin A (as retinol equivalent,	350.0	400.0	75.00	85.00

Sl. No.	Parameters	Limits		Limits per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
	RE), μg per 100 g				
10.	Vitamin D (expressed as cholecalciferol or ergocalciferol), μg per 100 g	5.0	10.0	1.00	2.10
11.	Vitamin E (alpha tocopherol equivalent), mg per 100 g	2.50	6.0	0.50	1.30
12.	Vitamin K, μg per 100 g	7.50	15.0	1.60	3.20
13.	Vitamin C, mg/ per 100 g (as ascorbic acid)	25.0	40.0	5.30	8.50
14.	Thiamine, μg per 100 g	200.0	300.0	42.60	63.80
15.	Riboflavin, μg per 100 g	400.0	2000.0	85.10	425.50
16.	Niacin equivalent, μg per 100 g	3800.0	5500.0	808.50	1170.20
17.	Pyridoxine, μg per 100 g	100.0	400.0	21.30	85.10
18.	Dietary Folate equivalent (DFE) (Folic acid), μg per 100 g*	15.0	50.0	3.20	10.60
19.	Pantothenic acid, μg per 100 g	2000.0	10000.0	425.50	2127.70
20.	Vitamin B12, μg per 100 g	0.25	0.50	0.050	0.10
21.	Biotin, μg per 100 g	7.50	50.0	1.60	10.60
22.	Choline, mg per 100 g	32.0	-	6.80	-
23.	Sodium, mg per 100 g	90.0	300.0	19.10	63.80
24.	Potassium, mg per 100 g	300.0	900.0	63.80	191.50
25.	Chloride, mg per 100 g	250.0	800.0	53.20	170.20
26.	Calcium, mg per 100 g	250.0	500.0	53.20	106.40
27.	Phosphorous, mg per 100 g	125.0	500.0	26.60	106.40
28.	Calcium : Phosphorus ratio	1:1	2:1	1:1	2:1
29.	Magnesium, mg per 100 g	30.0	40.0	6.40	8.50
30.	Iron, mg per 100 g	3.0	5.0	0.60	1.0
31.	Iodine, μg per 100 g	90.0	120.0	19.10	25.50
32.	Copper, μg per 100 g	160.0	470.0	34.0	100.0
33.	Zinc, mg per 100 g	2.50	5.0	0.50	1.0
34.	Manganese, μg per 100 g	5.0	500.0	1.0	106.40
35.	Selenium, μg per 100 g	5.0	17.0	1.00	3.60

* 1 microgram DFE = 0.6 microgram folic acid

(v) In addition, the product may also contain optional ingredients as provided in regulation 5(2)(viii).

(3) Food additives: No food additives are permitted in infant milk food. However, food additives shown in Schedule I (d) for special nutrient formulations may be used.

5. Infant formula

(1) Scope: This standard applies to infant formula in powder or liquid form for meeting the normal nutritional requirements of infant.

(2) Composition: (i) Infant formula is a product based on milk of cow or buffalo or mixture thereof, and other nutrients and ingredients which have been provided under these regulations.

(ii) The product may be modified by partial removal or substitution of different milk solids and addition of carbohydrates such as sucrose, dextrose, maltose, lactose and maltodextrin; and salts such as phosphates and citrates.

(iii) The infant formula may contain vegetable oils rich in polyunsaturated fatty acids to partially substitute milk fat. Hydrogenated vegetable oils and fats shall not be used in infant formula.

(iv) Infant formula may contain gluten free pre-cooked and/or gelatinized starches up to 30% of total carbohydrates in powder and upto 2 g/100 ml in liquid.

(v) Only lactic acid producing bacteria listed under schedule VII of the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 may be used along with other requirements laid down under the same regulations.

(vi) The product shall be uniform and free from lumps and coarse particles. It shall be free from rancid taste and musty odour.

(vii) The infant formula shall conform to the following requirements, namely:

Sl. No.	Parameters	Limits		Limits per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
1.	Moisture, percent by weight	-	4.5	-	-
2.	Energy per 100 ml of the product prepared in accordance with the manufacturer's instructions	60 kcal	70 kcal	-	-
3.	Total Protein (N x 6.25*), per cent by weight	10.0	16.0	2.10	3.40
4.	Total fat, g per 100 g Milk fat, g per 100 g	18.0 12.0	25.0 -	3.80 2.50	5.30 -
5.	a) Linoleic acid, g per 100 g b) α-Linolenic acid, mg per 100 g c) Ratio of Linoleic acid/α-Linolenic acid	1.50 250.0 6:1	7.0 - -	0.30 53.20 6:1	1.50 - -
6.	Sum of lauric and myristic acids, per cent by weight of total fatty acids Erucic acid, percent by weight of total fatty acids	- -	20.0 1.0	- -	4.25 0.20
7.	Trans fatty acids, percent by weight of total fatty acids	-	3.0	-	-

Sl. No.	Parameters	Limits		Limits per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
8.	Carbohydrates, per cent by weight a. Galactooligosaccharides and / or fructooligosaccharides, per cent of carbohydrates	45.0 -	70.0 10.0	9.60 -	14.90 2.10
9.	Total ash, percent by weight	-	8.50	-	-
10.	Ash insoluble in dilute hydrochloric acid, per cent by weight	-	0.10	-	-
11.	Vitamin A (as retinol equivalent, RE), µg per 100 g	350.0	400.0	75.0	85.0
12.	Vitamin D (expressed as cholecalciferol or ergocalciferol), µg per 100 g	5.0	10.0	1.0	2.10
13.	Vitamin E (alpha tocopherol equivalent), mg per 100 g	2.50	6.0	0.50	1.30
14.	Vitamin K, µg per 100 g	7.50	15.0	1.60	3.20
15.	Vitamin C, mg per 100 g (expressed as ascorbic acid)	25.0	40.0	5.30	8.50
16.	Thiamine, µg per 100 g	200.0	300.0	42.50	63.80
17.	Riboflavin, µg per 100 g	400.0	2000.0	85.10	425.50
18.	Niacin equivalent, µg per 100 g	3800.0	5500.0	808.50	1170.20
19.	Pyridoxine, µg per 100 g	100.0	400.0	21.30	85.10
20.	Dietary Folate equivalent (DFE) (Folic acid), µg per 100 g#	15.0	50.0	3.20	10.60
21.	Pantothenic acid, µg per 100 g	2000.0	10000.0	425.50	2127.60
22.	Vitamin B12, µg per 100 g	0.25	0.50	0.05	0.10
23.	Biotin, µg per 100 g	7.50	50.0	1.60	10.60
24.	Choline, mg per 100 g	32.0	-	6.80	-
25.	Sodium, mg per 100 g	90.0	300.0	19.15	63.80
26.	Potassium, mg per 100 g	300.0	900.0	63.82	191.48
27.	Chloride, mg per 100 g	250.0	800.0	53.20	170.20
28.	Calcium, mg per 100 g	250.0	700.0	53.20	148.90
29.	Phosphorous, mg per 100 g	125.0	500.0	26.60	106.40
30.	Calcium : Phosphorus ratio	1:1	2:1	1:1	2:1
31.	Magnesium, mg per 100 g	30.0	40.0	6.40	8.50
32.	Iron, mg per 100 g	3.0	5.0	0.60	1.0
33.	Iodine, µg per 100 g	90.0	120.0	19.15	25.50
34.	Copper, µg per 100 g	160.0	470.0	34.0	100.00
35.	Zinc, mg per 100 g	2.50	5.0	0.50	1.0
36.	Manganese, µg per 100 g	5.0	500.0	1.0	106.40
37.	Selenium, µg per 100 g	5.0	17.0	1.0	3.60

* where milk protein is used, a factor N x 6.38 may be used

#1 microgram DFE = 0.6 microgram folic acid

(viii) Optional Ingredients: when prepared in accordance with instructions for use infant formula may contain other nutrients which are ordinarily found in human milk in amounts prescribed below:

Sl. No.	Ingredient	Limits, mg per 100 g / ml	
		Minimum	Maximum
1	Carotenes	0.025	-
2	Amino acids (L forms)	0.90	-
3	Non-protein nitrogen	17.0	-
4	Nucleotides	1.17	-
5	L-carnitine	1.13	-
6	Lactalbumin	140.0	-
7	Lactoferrin	30.0	-
8	Lysozyme	80.0	-
9	Glucosamine	70.0	-
10	Inositol	3.0	-
11	Citric acid	35.0	-
12	Cholesterol	8.80	-
13	Fucose	130.0	-
14	Lipid phosphorous	0.70	-
15	Prostaglandins	PGE 15.0 PGF 40.0	-
16	Taurine	-	60.0
17	Molybdenum, μg	7.50	50.0
18	Chromium, μg	7.50	50.0

(3) Food additives: (i) Infant formula shall be free from added colour and flavour. The following food additives may be used in the preparation of infant formula ready for consumption prepared following manufacturer's instructions, unless otherwise indicated:

INS No.	Additive	Maximum Level (g per 100 ml)
Thickeners		
410	Carob bean gum	0.1
407	Carrageenan	0.03 (in regular milk and soy based liquid infant formula only)
Emulsifiers		
322	Lecithin	0.5
471	Mono- and diglycerides	0.4
472c	Citric and fatty acid esters of glycerol	0.9 (in all types of liquid infant formula) 0.75 (in all types of powdered infant formula)
Acidity Regulators		
524	Sodium hydroxide	0.2 (singly or in combination and within the limits for sodium, potassium and calcium in regulation 5(2)(vii)
500ii	Sodium hydrogen carbonate	
500i	Sodium carbonate	
501iii	Potassium hydrogen carbonate	
501i	Potassium carbonate	

INS No.	Additive	Maximum Level (g per 100 ml)
525	Potassium hydroxide	
526	Calcium hydroxide	
270	L(+) lactic acid	GMP
330	Citric acid	GMP
331i	Sodium dihydrogen citrate	GMP
331iii	Trisodium citrate	GMP
332	Potassium citrate	GMP
339 i, ii and iii	Sodium dihydrogen phosphate, disodium hydrogen phosphate and trisodium phosphate	45 mg as phosphorous singly or in combination and within limits for sodium, potassium and phosphorous in 5.(2)(vii)
340 i, ii and iii	Potassium dihydrogen phosphate, dipotassium hydrogen phosphate and tripotassium phosphate	
Antioxidants		
307b	Mixed tocopherol concentrate	1 mg (singly or in combination)
304i	Ascorbyl palmitate	1 mg (singly or in combination)
Packaging gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP

(ii) Food additives shown in Schedule I (d) for special nutrient formulations may also be used.

6. Milk cereal based complementary Food

(1) Scope: This standard applies to milk cereal based complementary food in powder form intended to complement the diet of infant.

(2) Composition: (i) Milk cereal based complementary food is based on milk of cow or buffalo or mixture thereof, and/or other nutrients/ingredients which have been provided under these regulations.

(ii) It may contain a variety of cereals, pulses, soybean and millets.

(iii) It may also contain edible vegetable oil, defatted edible oil seed extracts, protein concentrates / protein isolates, milk solids, various carbohydrates such as sucrose, dextrose, maltose, lactose, and malto dextrin, and salts such as phosphates and citrates. It shall not contain hydrogenated fats.

(iv) It may contain fruits and vegetables or their products, egg or egg products, and nuts or their products.

(v) The product shall be free from lumps and coarse particles, and shall be uniform in appearance. It shall be free from rancid taste and musty odour.

(vi) The milk cereal based complementary food shall conform to the following requirements, namely:

Sl. No.	Parameters	Limits		Limits per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
1.	Moisture, percent by weight	-	5.0	-	-
2.	Total Protein, per cent by weight (N x 6.25) Milk Protein, per cent by weight	15.0 5.0	- -	3.20 1.0	- -
3.	Total fat, per cent by weight (including milk fat) Milk fat (alone), percent by weight	7.50 5.0	- -	1.60 1.0	- -
4.	Total Carbohydrates, per cent by weight	55.0	-	11.70	-
5.	Total ash, per cent by weight	-	5.0	-	-
6.	Ash insoluble in dilute hydrochloric acid; per cent by weight	-	0.10	-	-
7.	Crude fibre (on dry basis), percent by weight	-	1.0	-	-
8.	Vitamin A (as retinol equivalent, RE), μg per 100 g	350.0	400.0	75.0	85.0
9.	Vitamin D, μg per 100 g (expressed as cholecalciferol or ergocalciferol)	5.0	10.0	1.0	2.10
10.	Vitamin C, mg to per 100 g	25.0	40.0	5.30	8.50
11.	Thiamine (as hydrochloride), mg per 100 g	0.20	0.30	0.04	0.06
12.	Riboflavin, mg per 100 g	0.40	2.0	0.08	0.40
13.	Niacin equivalent, mg per 100 g	3.80	5.50	0.80	1.20
14.	Dietary Folate equivalent (DFE) (Folic acid), μg per 100 g*	15.0	50.0	3.20	10.60
15.	Iron, mg per 100 g	3.0	5.0	0.60	1.0
16.	Zinc, mg per 100 g	2.50	5.0	0.50	1.0

*1 microgram DFE = 0.6 microgram folic acid

(vii) Optional Ingredient / Nutrient: It may also contain optional ingredient / nutrient as below:

S. No.	Ingredient / Nutrient	Limits per 100 g		Limits per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
1.	Pantothenic acid, mg	2.0	10.0	0.40	2.10
2.	Vitamin B 12, μg	0.25	0.50	0.07	0.10
3.	Vitamin K, μg	7.50	15.0	1.60	3.20

S. No.	Ingredient / Nutrient	Limits per 100 g		Limits per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
4.	Choline, mg	-	32.0	-	6.80
5.	Inositol, mg	20.0	200.0	4.25	42.55
6.	Calcium, mg	250.0	700.0	53.20	14.90
7.	Phosphorus, mg	125.0	500.0	26.60	106.40
8.	Chloride, mg	250.0	800.0	53.20	170.20
9.	Magnesium, mg	30.0	40.0	6.40	8.50
10.	Sodium, mg	90.0	300.0	19.15	63.80
11.	Selenium, µg	5.0	17.0	1.0	3.60
12.	Taurine, mg	-	60.0	-	12.75
13.	L-amino acids, mg	0.9	-	0.20	-
14.	L-Carnitine, mg	5.0	-	1.0	-
15.	Biotin, µg	7.50	50.0	1.60	10.60
16.	Iodine, µg	90.0	120.0	19.15	25.50
17.	Potassium, mg	300.0	900.0	63.80	191.50
18.	Pyridoxine, µg	100.0	400.0	21.30	85.10

(3) Food Additives: (i) Milk cereal based complementary food shall be free from preservatives, added colours and flavours. The following food additives may be used in preparation of Milk cereal based complementary food for consumption prepared following manufacturer's instructions, unless otherwise indicated.

INS No.	Additive	Maximum Level g per 100 g
Thickeners		
410	Carob bean gum	0.1
1412	Distarch phosphate	0.5 (singly or in combination)
1414	Acetylated distarch phosphate	
407	Carrageenan	0.03 (in soy based Infant Formula)
Emulsifiers		
322	Lecithins	0.5
471	Mono- and diglycerides	0.4
Acidity Regulators		
524	Sodium hydroxide	0.2 (singly or in combination and within the limits for sodium, potassium and calcium in 6.(2)(vii)
500ii	Sodium hydrogen carbonate	
500i	Sodium carbonate	
501iii	Potassium hydrogen carbonate	
501i	Potassium carbonate	
525	Potassium hydroxide	
526	Calcium hydroxide	

INS No.	Additive	Maximum Level g per 100 g
270	L(+) lactic acid	GMP
330	Citric acid	GMP
331i	Sodium dihydrogen citrate	GMP
331iii	Trisodium citrate	GMP
332	Potassium citrate	GMP
Antioxidants		
307b	Mixed tocopherol concentrate	1 mg
304i	Ascorbyl palmitate	1 mg
Packaging gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP
Enzymes		
	Alpha Amylase	GMP

(ii) Food additives shown in Schedule I (d) for special nutrient formulations may also be used.

(4) The milk cereal based complementary food prepared in the community kitchens (freshly prepared and distributed without storing) shall meet all the hygiene requirements specified by the FSSAI..

7. Processed cereal based complementary Food

(1) Scope: This standard applies to processed cereal based complementary food in powder form intended to complement the diet of infant.

(2) Composition: (i) Processed cereal based complementary food is a product based on variety of cereals, pulses including soybean, millets, nuts and edible oil seeds.

(ii) It shall contain milled cereals and legumes combined accounting for not less than 75 per cent.

(iii) Where the product is intended to be mixed with water or milk before consumption, the minimum content of protein shall be 15 per cent. by weight.

(iv) Protein Efficiency Ratio (PER) of processed cereal based complementary food shall not be less than 70 per cent. of that of casein.

(v) The Sodium content of the product shall not exceed 100 mg per 100 kcals of the ready-to-eat product.

(vi) It may also contain other ingredients such as protein concentrates, essential amino acids, milk and milk products, eggs and egg products, edible vegetable oils, defatted edible oil seed extracts, fruits and vegetables or their products, nuts or their products, various carbohydrates such as sucrose, dextrose, lactose, maltodextrin, honey, corn syrup and malt. It shall not contain hydrogenated vegetable fats.

(vii) The product shall be free from lumps and coarse particles, and shall be uniform in appearance. It shall be free from rancid taste and musty odour.

(viii) It may also contain probiotic ingredient(s) as provided under schedule VII of the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016.

(ix) It shall conform to the following requirements, namely:

S. No.	Parameters	Limits		Limits per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
1.	Moisture, percent by weight	-	5.0	-	-
2.	Protein (N x 6.25), Percent by weight	15.0	-	3.20	-
3.	Total Fat, per cent by weight	-	7.50	-	1.60
4.	Total Carbohydrates, per cent by weight	55.0	-	11.70	-
5.	Total ash, percent by weight	-	5.0	-	-
6.	Ash insoluble in dilute Hydrochloric acid, percent by weight	-	0.10	-	-
7.	Crude fibre (on dry basis), percent by weight	-	1.0	-	-
8.	Vitamin A (as retinol equivalent, RE), µg per 100 g	350.0	400.0	75.0	85.0
9.	Vitamin D, µg per 100 gm (expressed as cholecalciferol or ergocalciferol)	5.0	10.0	1.0	2.10
10.	Vitamin C, mg per 100 g	25.0	40.0	5.30	8.50
11.	Thiamine (as hydrochloride), mg per 100 g	0.20	0.30	0.04	0.06
12.	Riboflavin, mg per 100 g	0.40	2.0	0.08	0.40
13.	Niacin equivalent, mg per 100 g	3.80	5.50	0.80	1.20
14.	Dietary Folate equivalent (DFE) (Folic acid), µg per 100 g*	15.0	50.0	3.20	10.60
15.	Iron, mg per 100 g	3.0	5.0	0.60	1.0
16.	Zinc, mg per 100 g	2.50	5.0	0.50	1.0
17.	Pantothenic acid, mg per 100 g	2.0	10.0	0.40	2.10
18.	Pyridoxine, µg per 100 g	100.0	400.0	21.30	85.10
19.	Vitamin B12, µg per 100 g	0.25	0.50	0.05	0.10
20.	Biotin, µg per 100 g	7.50	50.0	1.60	10.60
21.	Choline, mg per 100 g	32.0	-	6.80	-
22.	Inositol, mg per 100 g	20.0	200.0	4.25	42.55
23.	Selenium, µg per 100g	5.0	17.0	1.0	3.60

*1 microgram DFE = 0.6 microgram folic acid

(3) Food Additives: (i) The Product shall be free from preservatives, added colours and flavours. Following additives are permitted in the preparation of Grain based Complementary food for infants in 100 g of the product ready for consumption prepared following manufacturer's instructions unless otherwise indicated.

INS No.	Additive	Maximum Level
Emulsifiers		
322	Lecithins	1500 mg
471	Mono- and diglycerides	5000 mg singly or in combination
472a	Acetic fatty acid esters of glycerol	
472b	Lactic fatty acid esters of glycerol	
472c	Citric acid fatty acid esters of glycerol	
Acidity regulators		
500ii	Sodium hydrogen carbonate	GMP
501ii	Potassium hydrogen carbonate	GMP
170i	Calcium carbonate	GMP
270	L(+)lactic acid	GMP
260	Acetic acid	GMP
261	Potassium acetate	GMP
262i	Sodium acetate	GMP
296	Malic acid (DL)-L(+) form	GMP
325	Sodium lactate (solution)-L(+) form	GMP
326	Potassium lactate (solution)-L(+) form	GMP
327	Calcium lactate-L(+) form	GMP
331i	Monosodium citrate	GMP
331ii	Trisodium citrate	GMP
332i	Monopotassium citrate	GMP
32ii	Tripotassium citrate	GMP
333	Calcium citrate	GMP
507	Hydrochloric acid	GMP
524	Sodium hydroxide	GMP
525	Potassium hydroxide	GMP
526	Calcium hydroxide	GMP
575	Glucono-delta-lactone	GMP
334	L(+)Tartaric acid	500 mg singly or in combination
335i	Monosodium tartarate	
335ii	Disodium tartarate	
336i	Mono potassium tartarate –L(+) form	
338	Ortho phosphoric acid	only for pH adjustment; 440 mg singly or in combination as phosphorous
339i	Mono sodium ortho phosphate	
339ii	Disodium orthophosphate	
339iii	Trisodium orthophosphate	

INS No.	Additive	Maximum Level
340i	Monopotassium orthophosphate	
340ii	Dipotassium orthophosphate	
340iii	Tripotassium orthophosphate	
341i	Monocalcium orthophosphate	
341ii	Dicalcium orthophosphate	
341iii	Tricalcium orthophosphate	
Antioxidants		
306	Mixed tocopherol concentrate	300 mg/Kg fat or oil singly or in combination of tocopherol
307	Alpha tocopherol	
304	L-ascorbyl palmitate	200 mg/kg fat or oil
300	L-ascorbic acid	50 mg expressed as ascorbic acid
301	Sodium ascorbate	
303	Potassium ascorbate	
302	Calcium ascorbate	20 mg expressed as ascorbic acid
Raising agent		
503i	Ammonium carbonate	GMP
503ii	Ammonium hydrogen carbonate	GMP
500i	Sodium carbonate	GMP
500ii	sodium hydrogen carbonate	GMP
Thickeners		
410	Carob bean gum	1000 mg singly or in combination
412	Guar gum	
414	Gum Arabic	
1404	Oxidized starch	5000 mg singly or in combination
1410	Mono starch phosphate	
1412	Distarch phosphate	
1413	Phosphated distarch phosphate	
1414	Acetylated distarch phosphate	
1422	Acetylated distarch adipate	
1420	Starch acetate esterified with acetic anhydride	
1450	Starch sodium octenyl succinate	
1451	Acetylated oxidized starch	
Anticaking agent		
551	Silicon dioxide	GMP
Packaging gases		

INS No.	Additive	Maximum Level
290	Carbon dioxide	GMP
941	Nitrogen	GMP
Enzymes		
	Alpha amylase	GMP

(ii) Food additives shown in Schedule I (d) for special nutrient formulations may also be used.

(4) The processed cereal based complementary foods for use in specific conditions, where protein needs to be restricted and where other cereals like wheat, soya, legumes and milk cannot be used, such processed cereal based complementary foods shall be prepared with single cereal like rice or ragi, which shall have the minimum protein content of 6-9 per cent, such products shall be conspicuously labelled, "mono grain based complementary foods for use in specific conditions under medical guidance only".

(5) Process cereal based complementary food prepared in the community kitchens shall meet all the hygienic requirements specified by the FSSAI and freshly prepared and distributed and not stored.

8. Follow-up Formula

(1) Scope: This standard applies to the composition of Follow-up formula. The product shall be nutritionally adequate to contribute to normal growth and development when used in accordance with its directions for use. Follow-up formula, in powdered form requires water for preparation.

(2) Composition: (i) Follow-up formula is a product based on milk of cow or buffalo or mixture thereof, and other nutrients and ingredients provided under these regulations.

(ii) The follow-up formula shall have protein content minimum of 3 g per 100 kcal derived from whole or skimmed milk or with minor modification that does not substantially impair the vitamin or mineral content of milk and which represents a minimum of 90 % of total protein.

(iii) The quality of protein shall not be less than 85 % of that of casein.

(iv) Fat not less than 3 g and not more than 6 g per 100 kcal. Linoleic acid in fat shall not be less than 300 mg per 100 kcal.

(v) The product shall contain nutritionally available carbohydrates suitable for feeding in such quantities so as to adjust the product to the energy density given below;

(a) 100 ml of ready-to-use formula when prepared in accordance with instructions for use shall provide 60 to 85 kcal of energy.

(vi) The product shall be free from lumps and coarse particles, and shall be uniform in appearance. It shall be free from rancid taste and musty odour.

(vii) The product may contain vegetable proteins.

(viii) The Product shall conform to the following requirements, namely:

S. No.	Parameters	Limits		Limits Per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
1.	Moisture, percent by weight	-	4.50	-	-
2.	Total ash, per cent by weight	-	8.50	-	-
3.	Ash insoluble in dilute hydrochloric acid, per cent by weight	-	0.10	-	-
4.	Vitamin A (as retinol equivalent, RE), µg per 100 g	350.0	400.0	75.0	85.0
5.	Vitamin D (expressed as Cholecalciferol or ergo calciferol), µg per 100 g	5.0	10.0	1.0	2.10
6.	Vitamin E (as alpha-tocopherols), mg per 100 g	2.50	6.0	0.50	1.30
7.	Vitamin K, µg per 100 g	7.50	15.0	1.60	3.20
8.	Vitamin C, mg per 100 g	25.0	40.0	5.30	8.50
9.	Thiamine, µg per 100 g	200.0	300.0	42.55	63.80
10.	Riboflavin, µg per 100g	400.0	2000.0	85.10	425.50
11.	Niacin, equivalent mg per 100 g	3.80	5.50	0.80	1.20
12.	Pyridoxine, µg per 100 g	100.0	400.0	21.30	85.10
13.	Dietary Folate equivalent (DFE) (Folic acid), µg per 100 g*	15.0	50.0	3.20	10.60
14.	Pantothenic acid, mg per 100 g	2.0	10.0	0.40	2.10
15.	Vitamin B12, µg per 100 g	0.25	0.50	0.05	0.10
16.	Choline, mg per 100 g	32.0	-	6.80	-
17.	Biotin, µg per 100 g	7.50	15.0	1.60	3.20
18.	Sodium, mg per 100 g	90.0	300.0	19.15	63.80
19.	Potassium, mg per 100 g	300.0	900.0	63.80	191.50
20.	Chloride, mg per 100 g	250.0	800.0	53.20	170.20
21.	Calcium, mg per 100 g	405.0	800.0	86.20	170.20
22.	Phosphorus, mg per 100 g	270.0	500.0	57.45	106.40
23.	Magnesium, mg per 100 g	30.0	40.0	6.40	8.50
24.	Iron, mg per 100 g	3.0	5.0	0.60	1.0
25.	Iodine, µg per 100 g	90.0	120.0	19.15	25.50
26.	Copper, µg per 100 g	160.0	470.0	34.0	100.0
27.	Zinc, mg per 100g	2.50	5.0	0.50	1.0

S. No.	Parameters	Limits		Limits Per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
28.	Manganese, µg per 100 g	5.0	50.0	1.0	10.60
29.	Selenium, µg per 100 g	5.0	17.0	1.0	3.60
30.	Inositol, mg per 100 ml	-	40	-	8.50
31.	Taurine, mg per 100 g	-	60.0	-	12.75
32.	Essential Amino acids, mg per 100 ml	0.9	-	0.19	-

*1 microgram DFE = 0.6 microgram folic acid

(3) Food Additives: (i) It shall be free from added starch and colours. The following additives may be used in the preparation of Follow up formula ready for consumption prepared following manufacturer's instructions, unless otherwise indicated.

INS No.	Additive	Maximum Level g /100 g
Thickening agent		
412	Guar gum	0.1
410	Locust bean gum (carob bean gum)	0.5 (singly or in combination)
1412	Distarch phosphate	
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1414	Acetylated distarch adipate	2.5 (in hydrolyzed protein and / or Amino acid based product)
407	Carrageenan	0.03 (in milk and soy based product)
440	Pectins	1
Emulsifiers		
322	Lecithin	0.5
471	Mono- and diglycerides	0.4
pH adjusting agents		
500ii	Sodium hydrogen carbonate	limited by GMP within the limits for sodium in 8.(2)(viii)
500i	Sodium carbonate	
331i	Sodium citrate	
501ii	Potassium hydrogen carbonate	

INS No.	Additive	Maximum Level g /100 g
501i	*Potassium carbonate*	
332i	Potassium citrate	
525	Sodium hydroxide	
525	Potassium hydroxide	
526	Calcium hydroxide	
270	L(+) lactic acid L(+) lactic acid producing cultures	
330	Citric acid	
Antioxidants		
306	Mixed tocopherol concentrate	3 (singly or in combination)
307	Alpha tocopherol	
304	L-ascorbyl palmitate	5 mg singly or in combination expressed as ascorbic acid
300	L-ascorbic acid	
301	Sodium ascorbate	
302	Calcium ascorbate	
Flavours		
	Natural fruit extracts	GMP
	Vanilla extract	GMP
	Ethyl vanillin	5 mg
	Vanillin	5 mg

(ii) Food additives shown in Annexure I (d) for special nutrient formulations may also be used.

(4) The follow-up formula prepared in the community kitchens shall meet all the hygienic requirements specified by the FSSAI and freshly prepared and distributed and not stored.

9. Infant Formula for Special Medical Purpose (FSMP)

(A) Scope: This standard applies to Infant Formula for special Medical purpose in liquid or powdered form intended for use, where necessary, as a substitute for human milk or infant formula in meeting the special nutritional requirements arising from the disorder, disease or medical condition for whose *dietary* management the product has been formulated.

(B) Composition: (i) Infant formula for special medical purpose is a product based on ingredients (from known and well established sources) suitable for human consumption.

(ii) The composition of infant formula for special medical purpose shall be based on sound medical and nutritional principles. The nutritional safety and adequacy of the formula shall be scientifically demonstrated to support the growth and development of the infants for whom it is intended as appropriate for the specific products and indications. Their use shall be demonstrated by scientific evidence to be beneficial in the dietary management of the infants for whom it is intended.

(iii) The energy content and nutrient composition of the Formula for special Medical Purpose intended for infants shall be based on the requirements for Infant Formula specified under regulation 5(2)(vii) except for the *compositional provisions* which must be modified to meet the especial nutritional requirements arising from disease(s) for whose dietary management the product is specifically formulated, labelled and presented.

(iv) Optional ingredients: In addition to the compositional requirements listed under regulation 5(2)(vii)for infant formula, in order to provide substances ordinarily found in human milk or required other ingredients as specified under regulation 5(2)(viii) may be added to ensure that the formulation is suitable as the sole source of nutrition for the infant and for the dietary management of the disease, disorder or medical condition of the infant.

(v) The suitability for the intended special medical purpose, the suitability for the particular nutritional use of infants and the safety of these substances shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect.

(vi) Only L (+) lactic acid producing cultures may be used in the formulas for special medical purposes for infants if shown to be safe and appropriate for use in these vulnerable populations.

(1) Premature infant milk substitute: (a) The premature infant milk substitute is required for babies born before 37 weeks only and till they attain 40 weeks of age. In addition to the requirements specified under regulation 5(2)(vii) and 5(2)(viii) for Infant formula, the premature Infant Milk Substitutes shall also meet the following requirements:

(i) Protein content (N x 6.25) shall not be less than 10.6 and not more than 19.2 per cent by weight or not less than 2.25 and not more than 4.1 g per 100 kcal only till 40 weeks.
(ii) The energy content shall not be less than 70 kcal and not more than 80 kcal.
(iii) Mineral content: Not less than 2.35 per cent by weight or 0.5 g per 100 kcal.
(iv) Calcium: Phosphorus ratio shall be 2:1

(v) The Sodium, Potassium and Chloride combined together shall not be less than 40 milli equivalents per Litre when prepared in accordance with manufacturer's instructions.

(vi) Whey Protein : Casein ratio shall be 60 : 40

(vii) The products may contain added essential amino acids.

(b) The containers of infant milk substitute meant for premature baby or labels affixed thereto shall indicate the following additional information, namely: -

(i) the words [FOR THE PREMATURE BABY (BORN BEFORE 37 WEEKS)] in capital letters along with the product name in central panel;

(ii) a statement "RECOMMENDED TO BE TAKEN UNDER MEDICAL ADVICE ONLY" in capital letters.

(2) Lactose free – Lactose and sucrose free – and sucrose free – Infant milk substitutes: (a) In addition to the requirements specified under regulation 5(2)(vii) and 5(2)(viii) for Infant formula (*except milk fat*) the above Infant Milk Substitute shall also meet the following requirements:

(i) Soy-protein based, lactose free formula shall have soy protein and glucose, dextrose, dextrin/maltodextrin, maltose and/ or sucrose as carbohydrates.

(ii) Lactose content in lactose free and Lactose and sucrose free infant milk substitutes shall not exceed 0.05 per cent. by weight.

(iii) The fat content derived from vegetable oils shall not be less than 18 per cent. by weight in Lactose free and Lactose- and sucrose free Infant Milk Substitutes.

(b) The container of infant milk substitute for lactose or lactose and sucrose intolerant infants or label affixed thereto shall indicate conspicuously "LACTOSE-FREE or SUCROSE-FREE or LACTOSE and SUCROSE-FREE" in capital letters

(c) A statement "RECOMMENDED TO BE TAKEN UNDER MEDICAL ADVICE ONLY" and shall also bear the following statements, namely: -

"Lactose free Infant Milk Substitute should only be used in case of diarrhoea in infants due to lactose intolerance".

(d) The lactose free/sucrose free Infant Milk Substitute should be withdrawn if there is no improvement in symptoms of intolerance".

(3) Hypoallergenic infant milk substitutes – (a) In addition to the requirements specified under regulation 5(2)(vii) and 5(2)(viii) for Infant formula except for milk fat and milk protein, the hypoallergenic infant milk substitutes shall also meet the following requirement:

(i) Protein used shall be hydrolysed whey protein or casein or free amino acids.

(b) The product which contains neither milk nor any milk derivatives shall be labelled "contains no milk or milk products" in conspicuous manner.

(c) The container of infant milk substitute meant for infants with allergy to cow's / buffalo's milk protein shall indicate conspicuously "HYPOALLERGENIC FORMULA" and statement "RECOMMENDED TO BE TAKEN UNDER MEDICAL ADVICE ONLY" in capital letters on the label.

(4) Foods for Infants with Inborn Errors of Metabolism (IEM)

(a) Scope: This standard applies to food intended for the specific dietary management of disease of infants with specific inborn error(s) of metabolism. This food is intended to be given under medical supervision.

(b) Description: (i) A food for infant with IEM is a food which is formulated or processed to be consumed orally or administered enterally through a tube and is intended for the specific dietary management of a disease or a condition with distinctive nutritional requirements, based on well-established scientific studies and medical evaluation.

(ii) It is specially processed and formulated with nutrients desirable for the infant suffering from a specific IEM. The product should exclude the ingredients/nutrients that are harmful to the diseased infant. The essential characteristic involves a specific modification of the content or nature of proteins, fats or carbohydrates.

(iii) It is intended for the dietary management of an infant who, because of therapeutic or chronic needs has restricted, limited or impaired capacity to ingest, digest, absorb or metabolize ordinary foodstuffs or infant formula or certain nutrients or who needs specific nutrients established by medical observations.

(iv) Such foods fulfill unique nutritional needs of the infant with IEM through specific modifications/alterations and processing of the food components.

(c) Composition: (i) The composition of Medical food for infants with IEM shall be based on sound medical and nutritional principles. The nutritional safety and adequacy of the food shall be scientifically demonstrated to support the growth and development of infants with IEM. Their use shall be demonstrated by scientific evidence to be beneficial in the dietary management of the infants for whom it is intended.

(ii) Ingredients used in such food shall be suitable and safe and comply with all the applicable provisions of Food Safety and Standards Regulations. The product may have ingredients mentioned in regulation 5(2) of infant formula, such as milk, carbohydrates, vegetable oils, hydrolysed proteins, amino acids, or any other

ingredients required for the infants with IEM provided they are safe, desirable and nutritionally beneficial for infants with IEM.

(iii) The product may also have ingredients that are scientifically and medically proven to be necessary for such foods. However, prior approval of the authority has to be taken.

(iv) It may contain vitamins and minerals stated in regulation 5(2)(vii) for infant formula; provided such nutrients are safe, desirable and not harmful for infants suffering from IEM. Vitamins, minerals and amino acids for infants suffering from IEM may be added at levels greater than RDA specified based on scientific/ medical needs and under strict medical supervision.

(d) Food Additives: (i) In addition to the additives mentioned in regulation 5(3) for Infant formula, following food additives are permitted in the preparation of 100 ml of the product ready for consumption prepared following manufacturer's instructions, unless otherwise indicated:

INS No.	Additive	Maximum Level
Thickeners		
412	Guar gum	0.1 g in formulas containing hydrolysed protein
1412	Distarch phosphate	0.5 g singly or in combination in soya-based products 2.5 g singly or in combination in hydrolysed protein and/or amino acid based products
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1440	Hydorxy propyl starch	
415	Gum arabic	2000 mg in gluten free infant formulae
440	Pectins (amidated and non amidated)	
407	Carrageenan	0.1 g in hydrolysed protein and and/or amino acid based infant formula only
1450	Starch sodium octenyl succinate	2 g in hydrolysed protein and/or amino acid based infant formula only

(ii) Food additives shown in Schedule I (d) for special nutrient formulations may also be used.

(e) Labelling: (i) The words 'FOOD FOR SPECIAL MEDICAL PURPOSE' printed in the immediate proximity of the name or brand name of the product.

(ii) The statement "*For the Nutrition Management of IEM conditions* (*specific disease(s) , disorder(s) or medical condition(s) for which the product is intended, and for which it has been shown to be effective*) *such as* Maple syrup urine disease; Glutaric Acidemia Type 1; Homocystinuria; Isovaleric Acidemia, 3-Methylcrotonyl-CoA Carboxylase deficiency, 3-Methylglutaconyl-CoA Hydratase deficiency;

Methylmalonic Acidemias, Propionic Acidemia; Amino acid metabolic disorders; Phynylketonuria (PKU); Urea Cycle Disorders, Argininemia, Argininosuccinic Aciduria, Carbamoylphosphate Synthetase deficiency I, Citrullinemia; Tyrosinemia; Galactosemia; 3-Hydroxy Long Chain Acyl-CoA Dehydrogenase Deficiency; Defects in the intraluminal hydrolysis of fat; defective mucosal fat absorption defective lymphatic transport of fat; Disaccharidase deficiencies, Disorders of carbohydrate metabolism Sucrase / isomaltase deficiency, Fructose intolerance; Non-ketotic Hyperglycinemia, Lysinuric protein intolerance and Glucose transport defect (Glut 1def), Pyruvate dehydrogenase complex deficiency.

(iii) An advisory warning "RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY" appearing on the label in bold letters in an area separated from other written, printed or graphic information.

(iv) Information on osmolality or osmmolarity and/or acid-base balance shall be given when appropriate.

(v) Such foods in which essential characteristic involves a specific modification of the content or nature of proteins, fats or carbohydrates shall bear a description of this modification and information on the amino acid, fatty acid or carbohydrate profile when necessary.

(vi) A prominent statement indicating whether the product is or is not intended as the sole source of nutrition shall appear on the label.

(vii) Information of the nature of animal or plant proteins or protein hydrolysates should be provided.

(viii) Feeding instructions, including the method of administration and serving size if applicable, shall be given on the label.

(ix) A complete statement concerning adequate precautions, known side effects, contraindications and product-drug interaction, as applicable shall be given on the label.

(x) A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful.

(xi) If the product has been formulated for a specific age group, it should carry a prominent statement to that effect.

(xii) A statement specifying the nutrient(s) which have been reduced, omitted, increased or otherwise modified, relative to normal requirements and the rationale for the reduction, omission, increase or other modification shall appear on the label.

(xiii) A warning that the product is not for parenteral use.

10. Food for Infant based on Traditional food ingredients:

(1) Scope: This standard applies to Food for infants prepared using traditional food ingredients. These foods are intended for infants.

(2) Composition: (i) The composition of such foods shall be based on traditional food ingredients such as rice, rice flour, wheat flour, semolina, pulses and other cereals, fruits, dry fruits and vegetables, milk, ghee, egg and egg products.

(ii) Ingredients used shall be safe and comply with all the applicable provisions of Food safety and Standard Regulations, 2011.

(iii) The product may contain vitamins, minerals, amino acids and other nutrients necessary for Infant.

(iv) Such foods shall be either in the form "Ready to Use" or to be reconstituted with medium such as milk, water, curd or any other medium appropriate for infant. Clear instructions for use shall be provided on the label.

(v) These shall be manufactured adopting necessary and appropriate technologies during the process and packaging so that they retain their nutritional and other physical and sensory attributes.

(3) Food additives: They shall be free of any preservatives and colours.

(4) Labelling: (i) Such Products shall bear prominently the term "Traditional Food for Infants".

(ii) A prominent statement indicating whether the product is or is not intended as the sole source of nutrition shall appear on the label.

(iii) Feeding instructions including the method of administration and serving size, if applicable, and the nutrient values shall be given on the label.

(iv) If the product is intended for a specific age group, it should carry a prominent statement to that effect.

Explanatory note: A non-exhaustive examples of Foods for infants based on traditional foods are:

(1) Cooked lentils, cereals, dry fruits, grains mashed to a pasty form, sweetened with sugar or jaggery or honey
(2) Cooked vegetables mashed to a pasty form either sweetened or with little ghee
(3) Cooked rice made into a gruel or served with curd

(4) Cooked ganjee (cooked rice and made into a slightly thick liquid suitable for feeding
(5) Ragi malt mix
(6) Semolina or sooji based foods with either milk or curd or ghee.

Schedule I(a)

ADVISORY LISTS OF MINERAL SALTS FOR USE IN FOODS FOR INFANT NUTRITION

No.	Salts	Purity Requirements	Use in Foods for Infant Nutrition
1.	Source of Calcium (Ca)		
1.1.	Calcium carbonate	JECFA(1973),FCC,USP, BP, IP	IMF,IF, MCCF,FUF, FSMP
1.2.	Calcium chloride	JECFA(1975), FCC, USP, BP, IP	IMF,IF, MCCF, FUF, FSMP
1.3.	Calcium citrate (Tricalcium dicitrate)	JECFA(1975), FCC,USP, IP	IMF,IF, MCCF, FUF, FSMP
1.4.	Calcium gluconate	JECFA(1998),FCC USP, BP, IP	IMF,IF, MCCF, FUF, FSMP
1.5.	Calcium glycerophosphate	FCC, BP, IP	IMF,IF, MCCF, FUF, FSMP
1.6.	Calcium L- lactate	JECFA(1974), FCC,USP, BP, IP	IMF,IF, MCCF, FUF, FSMP
1.7.	Calcium phosphate, monobasic (Calcium dihydrogen phosphate)	JECFA(1996), FCC, IP	IMF,IF, MCCF, FUF, FSMP
1.8.	Calcium phosphate, dibasic (Calcium hydrogen phosphate)	JECFA(1975),FCC,BP, IP	IMF,IF, MCCF, FUF, FSMP
1.9.	Calcium phosphate, tribasic (Tricalcium dipohosphate)	JECFA(1973),FCC, BP, IP	IMF,IF, MCCF, FUF, FSMP
1.1(	Calcium oxide	JECFA(1975),FCC, IP	IMF,IF, MCCF, FSMP
1.1	Calcium sulphate	FCC, JECFA(1975), IP	FSMP
2.	Source of Phosphorus (P)		
2.1	Calcium phosphate, monobasic	FCC,JECFA(1996), IP	IMF,IF, MCCF, FUF, FSMP
2.2	Calcium phosphate, dibasic	FCC, JECFA(1975), IP	IMF,IF, MCCF, FUF, FSMP
2.3	Calcium phosphate, tribasic	FCC,JECFA(1973), IP	IMF,IF, MCCF, FUF, FSMP
2.4	Magnesium phosphate, dibasic	FCC, IP	
2.5	Magnesium phosphate,tribasic	FCC, IP	IMF,IF, MCCF, FUF, FSMP
2.6	Potassium phosphate,monobasic	FCC, IP	IMF,IF, MCCF, FUF, FSMP
2.7	Potassium phosphate, dibasic	FCC, IP	IMF,IF, MCCF, FUF, FSMP
2.8	Sodium phosphate, dibasic	FCC, IP	IMF,IF, MCCF, FUF, FSMP
2.9	Phosphoric acid	FCC, IP	IMF,IF, MCCF, FUF, FSMP

No.	Salts	Purity Requirements	Use in Foods for Infant Nutrition
3.	Source of Chloride (Cl)		
3.1	Calcium chloride	FCC, JECFA(1975), IP	IMF,IF, MCCF, FUF, FSMP
3.2	Choline chloride	FCC, IP	
3.3	Magnesium chloride	FCC, IP	IMF,IF, MCCF, FUF, FSMP
3.4	Manganese chloride	FCC, IP	IMF, IF
3.5	Potassium chloride	FCC, IP	IMF,IF, MCCF, FUF,FSMP
3.6	Sodium chloride	FCC, IP	IMF,IF, MCCF, FUF, FSMP
3.7	Hydrochloric acid (Food grade)	IP	IMF,IF, MCCF, FUF, FSMP
4.	Iron (Fe)		
4.1	Ferrous carbonate, stabilized With saccharose	DAB, IP	MCCF, PCCF, FSMP
4.2	Ferrous citrate	FCC, IP	IMF,IF, MCCF, PCCF,FUF, FSMP
4.3	Ferrous fumarate	FCC,USP, DAB,BP, IP	IF, MCCF, PCCF,FUF, FSMP
4.4	Ferrous gluconate	FCC, JECFA(1999), USP, DAB, BP, IP	IMF,IF, MCCF, PCCF, FUF, FSMP
4.5	Ferrous lactate	JECFA(1989),FCC, NF, IP	IMF,IF, MCCF, PCCF, FUF, FSMP
4.6	Ferrous succinate	MI, MI, IP	IMF,IF, MCCF, PCCF, FUF, FSMP
4.7	Ferrous sulphate	FCC, JECFA(1999), USP, BP, DAB, IP	IMF,IF, MCCF, PCCF,FUF, FSMP
4.8	Ferric ammonium citrate	JECFA(1984), FCC, IP	IMF,IF, MCCF, PCCF,FUF, FSMP
4.9	Ferric citrate	FCC, IP	IMF,IF, MCCF, PCCF,FUF, FSMP
4.10	Ferrous bisglycinate	JECFA (2003), IP	IMF,IF, MCCF, PCCF, FUF, FSMP
4.11	Sodium ferric pyrophosphate Ferric diphosphate	FCC, IP	IMF,IF, MCCF, PCCF,FUF, FSMP
4.12	Hydrogen reduced iron	FCC, DAB, IP	IF, MCCF, PCCF, FSMP
4.13	Electrolytic iron	FCC, IP	IF, MCCF, PCCF, FSMP
4.14	Carbonyl iron	FCC, IP	IF, MCCF, PCCF, FSMP
4.15	Ferric orthophosphate	FCC, IP	MCCF, PCCF
5.	Source of Magnesium (Mg)		
5.1	Magnesium carbonate	JECFA(1979), USP, BP, IP	IMF,IF, MCCF, FUF, FSMP
5.2	Magnesium chloride	FCC, JECFA(1979), USP, BP, IP	IMF,IF, MCCF, FUF, FSMP
5.3	Magnesium oxide	FCC, JECFA(1973), USP,	IMF,IF, MCCF, FUF,

No.	Salts	Purity Requirements	Use in Foods for Infant Nutrition
		BP, IP	FSMP
5.4	Magnesium phosphate, dibasic (Magnesium hydrogen Phosphate)	FCC, JECFA(1982), IP	IF, MCCF, FUF, FSMP
5.5	Magnesium phosphate,tribasic(Trimagnesium phosphate)	FCC, JECFA(1982), IP	IMF,IF, MCCF, FUF, FSMP
5.6	Magnesium sulphate Magnesium gluconate	FCC, USP, BP, IP JECFA(1998),FCC, IP	IMF,IF, MCCF, FUF, FSMP IMF,IF, MCCF, FUF, FSMP
6.	Source of Sodium (Na)		
6.1	Sodium bicarbonate	FCC, JECFA(1975), USP, NF, IP	IMF,IF,FUF, FSMP
6.2	Sodium carbonate	FCC, JECFA(1975), USP, NF, IP	IMF,IF,FUF, FSMP
6.3	Sodium chloride	FCC, USP, BP, IP	IMF,IF,FUF, FSMP
6.4	Sodium citrate (Trisodium citrate)	JECFA(1975), USP, BP, DAB, IP	IMF,IF,FUF, FSMP
6.5	Sodium gluconate	FCC, JECFA(1995), USP, IP	IMF,IF, FSMP
6.6	Sodium L- lactate	JECFA(1974), FCC, USP, BP, IP	IMF,IF,FUF, FSMP
6.7	Sodium phosphate, monobasic (sodium dihydrogen phosphate	JECFA(1963), FCC, USP, IP	IMF,IF,FUF, FSMP
6.8	Sodium phosphate, dibasic (Disodium hydroghen phosphate)	JECFA(1975), FCC, USP, BP, IP	IMF,IF,FUF, FSMP
6.9	Sodium phosphate, tribasic (Trisodium phosphate)	FCC, JECFA91975), IP	IMF,IF,FUF, FSMP
6.10	Sodium sulphate	JECFA(2000), FCC, USP, BP, IP	IMF,IF,FUF, FSMP
7.	Source of Potassium (K)		
7.1	Potassium bicarbonate	FCC,JECFA(1979), USP, BP, IP	IMF,IF, MCCF,FUF, FSMP
7.2	Potassium carbonate	FCC, JECFA(1975), USP, BP, IP	IMF,IF, MCCF,FUF, FSMP
7.3	Potassium chloride	FCC, JECFA(1979), USP, BP, IP	IMF,IF, MCCF, FUF, FSMP
7.4	Potassium citrate (tripotassium citrate)	FCC, JECFA(1975), USP, BP, IP	IMF,IF, MCCF, FUF, FSMP
7.5	Potassium glycerophosphate	FCC, IP	PCCF, FSMP
7.6	Potassium gluconate	JECFA(1978), CC,USP, IP	IMF,IF, MCCF, FUF, FSMP
7.7	Potassium phosphate, monobasic	FCC,JECFA(1982),FCC, BP, IP	IF, FUF, FSMP

No.	Salts	Purity Requirements	Use in Foods for Infant Nutrition
7.8	Potassium phosphate, dibasic	FCC,JECFA(1982),BP, IP	IF, FUF, FSMP
8.	Source of Copper (Cu)		
8.1	Copper gluconate	FCC, USP, IP	IMF,IF, FUF, FSMP
8.2	Cupric carbonate	MI, IP	IMF,IF,FUF, FSMP
8.3	Cupric citrate	FCC, USP, IP	IMF,IF,FUF, FSMP
8.4	Cupric sulphate	JECFA(1973), FCC, USP,DAB, IP	IMF,IF,FUF, FSMP
9.	Source of Iodine (I)		
	Potassium iodide	FCC, USP, BP, DAB, IP	IMF,IF, MCCF, FUF, FSMP
9.1	Sodium iodide	USP, BP, DAB, IP	IMF,IF, MCCF, FUF, FSMP
9.2	Potassium iodate	FCC, IP	FSMP
9.3	Sodium iodate	FCC, IP	FSMP
10.	Source of Zinc (Zn)		
10.1	Zinc acetate	USP, IP	IMF,IF, MCCF,FUF,PCCF, FSMP
10.2	Zinc chloride	USP, BP, DAB, IP	IMF,IF, MCCF,FUF,PCCF, FSMP
10.3	Zinc oxide	FCC, USP, DAB, BP, IP	IMF,IF, MCCF,FUF,PCCF, FSMP
10.4	Zinc sulphate	FCC, USP, BP, IP	IMF,IF, MCCF,FUF,PCCF, FSMP
11.	Source of Manganese (Mn)		
11.1	Manganese carbonate	MI, IP	IMF,IF, FUF, FSMP
11.2	Manganese chloride	FCC, IP	IMF,IF,FUF, FSMP
11.3	Manganese citrate	FCC, IP	IMF,IF,FUF, FSM
11.4	Manganese sulphate	FCC, USP, IP	IMF,IF, FUF, FSMP
11.5	Manganese gluconate	FCC, IP	IMF,IF,FUF, FSMP
12.	Source for Selenium		
12.1	Sodium selenate	MI, IP	IMF,IF, PCCF, FUF, FSMP
12.2	Sodium selenite	Ph Eur, USP, MP, MI, IP	IMF, IF, PCCF, FUF, FSMP
12.3	Sodium hydrogen selenite	DVFA, IP	IMF, IF, PCCF, FUF, FSMP
13.	Source for Chromium (III)		
13.1	Chromium sulphate	USP, MI, IP	IF, FSMP
13.2	Chromium chloride	USP, MI, IP	IF, FSMP
14.	Source for Molybdenum (VI)		
14.1	Sodium molybdate	Ph Eur, IP	IF, FSMP

No.	Salts	Purity Requirements	Use in Foods for Infant Nutrition
14.2	Ammonium molybdate	FCC, USP, IP	IF, FSMP

Schedule I(b)

ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANT NUTRITION

No.	Vitamin	Purity Requirements	Use in foods for infant Nutrition
1.	Vitamin A		
1.1	all trans retinol	FCC, USP, Ph Eur, IP	IMF, IF, MCCF, PCCF,FUF, FSMP
1.2	Retinyl acetate	FCC, USP, Ph Eur, IP	IMF, IF, MCCF, PCCF,FUF, FSMP
1.3	Retinyll palmitate	FCC., USP, Ph Eur, IP	IMF, IF, MCCF, PCCF,FUF,FSMP
2.	Provitamin A	Beta-carotene	
2.1	Beta-carotene	JECFA(1987), FCC, USP,Ph Eur, IP	IMF, IF ,FSMP
3.	Vitamin D		
3.1	Vitamin D_2(Ergocalciferol)	FCC, USP, Ph Eur, IP	IMF, IF, MCCF,PCCF,FUF, FSMP
3.2	Vitamin D_3(Cholecalciferol)	FCC, USP, BP, DAB, IP	IMF, IF, MCCF,PCCF,FUF FSMP
4.	Vitamin E		
4.1	D-alpha-Tocopherol	JECFA(2000), FCC, USP, NF,	IMF, IF, FUF FSMP
4.2	DL-alpha-Tocopherol	IP	IMF, IF, FUF, FSMP
4.3	D-alpha-Tocopheryl acetate	JECFA(1986), FCC, USP, NF, IP	IMF, IF, FUF, FSMP
4.4	DL-alpha-Tocopheryl acetate	FCC, USP, NF, BP, Ph Eur, IP	IMF, IF, FUF.FSMP
4.5	D-alpha-Tocopheryl acid succinate	FCC, USP, NF, BP, Ph Eur, IP	IMF, IF, FSMP
4.6	DL-alpha Tocopheryl acid succinate	FCC, USP, Ph Eur, IP	IMF, IF, FSMP
4.7	DL-alpha-Tocopheryl polyethylene glycol succinate	NF, MP, MI, USP, Ph Eur, IP	IMF, IF, FSMP
		FCC, USP, IP	
5.	Vitamin C		
5.1	L-Ascorbic acid	JECFA(1973), FCC, USP, Ph Eur, BP, Ph Eur, IP	IMF, IF, MCCF,PCCF,FUF FSMP
5.2	Calcium-L-ascorbate	JECFA(1981), FCC, USP, Ph Eur, IP	IMF, IF, MCCF,PCCF, FUF, FSMP
5.3	6-Palmitoyl-L-ascorbic acid	JECFA(1973), FCC, USP, BP, NF, Ph Eur, IP	IMF, IF, MCCF,PCCF,FUF, FSMP

No.	Vitamin	Purity Requirements	Use in foods for infant Nutrition
5.4 5.5	Sodium-L-ascorbate (Ascorbyl palmitate) Potassium-L-ascorbate	JECFA(1973), FCC, USP, Ph Eur, IP FCC, IP	IMF, IF, MCCF,PCCF,FUF, FSMP IMF, IF, MCCF,PCCF, FSMP
6.	Vitamin B_1		
6.1 6.2	Thiaminchloride hydrochloride Thiamin mononitrate	FCC, USP, Ph Eur, IP FCC, USP, BP, Ph Eur, IP	IMF, IF, MCCF,PCCF, FUF,FSMP IMF, IF, MCCF,PCCF,FUF, FSMP
7.	Vitamin B_2		
7.1 7.2	Riboflavin Riboflavin-5/-phosphate sodium	JECFA(1987), FCC, USP, BP, IP JECFA(1987), USP, BP, Ph Eur, IP	IMF, IF, MCCF,PCCF, FUF,FSMP IMF, IF, MCCF,PCCF, FUF,FSMP
8.	Niacin		
8.1 8.2	Nicotinic acid amide (Nicotinamide) Nicotinic acid	FCC, USP, Ph Eur, BP, IP FCC, USP, BP, Ph Eur, IP	IMF, IF, MCCF,PCCF, FUF, FSMP IMF, IF, F,PCCF,FUF, FSMP
9.	Vitamin B_6		
9.1 9.2	Pyridoxine hydrochloride Pyridoxal 5-phosphate	FCC, USP, BP, Ph Eur, IP MI, FCC, USP, IP	IMF, IF, MCCF,PCCF,FUF, FSMP IMF, IF, MCCF,PCCF, FUF,FSMP
10.	Folic acid		
10.1 10.2	N-Pteroyl-L-glutamic acid Calcium-L-methyl folate	FCC, USP, Ph Eur, IP JECFA(2005), IP	IMF, IF, MCCF,PCCF, FUF, FSMP IMF, IF, FSMP
11.	Pantothenic acid		
11.1 11.2 11.3 11.4	Calcium-D-pantothenate Sodium-D-pantothenate D-Panthenol DL-Panthenol	FCC, USP, Ph Eur, IP DAB, IP FCC, USP, Ph Eur, IP FCC, USP, Ph Eur, IP	IMF, IF, MCCF,PCCF, FUF,FSMP IMF, IF, MCCF,PCCF, FUF,FSMP, IMF, IF, MCCF,PCCF,FUF, FSMP IMF, IF, MCCF,PCCF, FUF,FSMP

No.	Vitamin	Purity Requirements	Use in foods for infant Nutrition
12.	Vitamin B_{12}		
12.1 12.2	Cyanocobalamine Hydroxo-cobalamine	FCC, USP, BP, PhEur, IP USP, NF, Ph Eur, IP	IMF, IF, MCCF,PCCF, FUF, FSMP IMF, IF, MCCF,PCCF,FUF, FSMP
13.	Vitamin K_1		
13.1	Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoQuinine/Phylloquinone/phytonadione)	FCC, USP, Ph Eur, BP, IP	IMF, IF, MCCF,PCCF, FUF, FSMP
14.	Biotin		
14.1	D-biotin	FCC, USP, Ph Eur, IP	IMF, IF,MCCF, PCCF, FUF,FSMP

Schedule I(c)

ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR INFANT NUTRITION UNDER THE PROVISIONS OF THE REGULATIONS

No.	Nutrient source	Purity requirements by
1.	Amino acids	
1.1	L-Arginine	FCC, USP, Ph Eur, BP, IP
1.2	L-arginine hydrochloride	FCC, USP, Ph Eur, BP, IP
1.3	L-Cystine	FCC, USP, Ph Eur, IP
1.4	L-Cystine dihydrochloride	MI, IP
1.5	L-Cysteine	DAB, IP
1.6	L-Cysteine hydrochloride	FCC, Ph Eur, IP
1.7	L-Histidine	FCC, USP, Ph Eur, IP
1.8	L-Histidine hydrochloride	FCC, Ph Eur, DAB, IP
1.9	L-isoleucine	FCC, USP, Ph Eur, IP
1.10	L-Isoleucine hydrochloride	FCC, USP, IP
1.11	L-Leucine	FCC, USP, Ph Eur, IP
1.12	L-Leucine hydrochloride	MI, FCC, USP, IP
1.13	L-Lysine	USP, IP
1.14	L-Lysine hydrochloride	FCC, USP, Ph Eur, IP
1.15	L-Methionine	FCC, USP, Ph Eur, IP
1.16	L-Phenylalanine	FCC, USP, Ph Eur, IP
1.17	L-Threonine	FCC, USP, Ph Eur, IP
1.18	L-Tryptophan	FCC, USP, Ph Eur, IP
1.19	L-Tyrosine	FCC, USP, Ph Eur, IP
1.20	L-Valine	FCC, USP, Ph Eur, IP

No.	Nutrient source	Purity requirements by
1.21	L-Alanine	FCC, USP, Ph Eur, IP
1.22	L-Arginine L-aspartate	Ph Eur, IP
1.23	L-Aspartic acid	FCC, USP, Ph Eur, IP
1.24	L-Citruline	USP, IP
1.25	L-Glutamic acid	JECFA(1987), USP, FCC, Ph Eur, IP
1.26	L-Glutamine	FCC, USP, Ph Eur, IP
1.27	Glycine	FCC, USP, Ph Eur, IP
1.28	L-Ornithine	MI, FCC, IP
1.29	L-ornithine monohydrochloride	DAB, IP
1.30	L-Proline	FCC, USP, Ph Eur, IP
1.31	L-Serine	USP, Ph Eur, IP
1.32	N-Acetyl-L-cysteine (N-Acetyl-L-methionine)	USP, Ph Eur, IP
1.33	L-Lysine acetate	FCC, USP, MP, Ph Eur, IP
1.34	L-Lysine-L-aspertate	Jap Food Stan, IP
1.35	L-Lysine-L-glutamate dihydrate	Jap Food Stan, IP
1.36	Magnesium L-aspartate	Ph Eur, IP
1.37	Calcium L-glutamate	JECFA, FCC, Jap Food Stan, IP
1.38	Potassium L-glutamate	JECFA, FCC, Jap Food Stan, IP
2.	Carnitine	
2.1	L-Carnitine	FCC, USP, Ph Eur, IP
2.2	L-Carnitine hydrochloride	FCC, IP
2.3	Carnitine tartrate	FCC, Ph Eur, IP
3.	Taurine	

No.	Nutrient source	Purity requirements by
3.1	Taurine	USP, JP, IP
4.	Choline	
4.1	Choline	FCC, USP, IP
4.2	Choline chloride	FCC, IP
4.3	Choline citrate	NF, IP
4.4	Choline hydrogen tartrate	DAB, IP
4.5	Choline bitartrate	FCC, NF, DAB, IP
5.	Inositols	
5.1	Myo-inositol	FCC, IP
6.	Nucleotides	
6.1	Adenosine 5-monophosphate (AMP)	FSANZ, IP
6.2	Cytidine 5-mono phosphate (CMP)	FSANZ, IP
6.3	Guanosine 5-mono phosphate (GMP)	JECFA (1985), IP
6.4	Inosine 5-mono phosphate (IMP)	JECFA (1974), IP
6.5	Disodium uridine 5-monophosphate salt	FSANZ, IP
6.6	Disodium guanosine 5-mono phosphate salt	FCC, JECFA, FSANZ, IP
6.7	Disodium ionosine 5-mono phosphate	FCC, JECFA, FSANZ, IP

As far as applicable, also the free, hydrated and anhydrous forms of amino acids and the hydrochloride, sodium and potassium salts of amino acids may be used in FSMP.

Schedule I(d)

LIST OF FOOD ADDITIVES THAT CAN BE ADDED FOR SPECIAL NUTRIENT FORMULATIONS

For reasons of stability and safe handling, some vitamins and other nutrients have to be converted into suitable preparations. For this purpose, the food additives included in respective specific standards may be used. In addition, the following food additives may be used as nutrient carriers.

INS No.	Additive/Carrier	Maximum level in ready-to use food For Infant Nutrition (mg/kg)
414	Gum Arabic/gum acacia or Galacto oligosaccharide	10
551	Silicon dioxide	10
421	Mannitol (for vitamin B_{12} dry rubbing, 0.1% only)	10
1450	Starch sodium octenyl succinate	100
301	Sodium L-ascorbate (in coating of nutrient preparations containing polyunsaturated fatty acids)	75

Abbreviations:
BP: British pharmacopoeia
DAB: Deutsches Arzneibuch
DVFA:DanishnVeterinary and Food administration
FCC : Food Chemicals Codex
FSANZ: Food Standards Australia and New Zealand
FSMP: Foods for Special Medical Purposes
FUF: follow up Formula
IMF: Infant Milk food
IF: Infant formula
IP : Indian Pharmacopoeia
Jap Food Stan: Japanese Food Standard
JECFA: FAO/WHO Joint Expert Committee on Food Additives.
MCCF: Milk cereal based complementary food
MI : Merck Index.
PCCF: Processed cereal based complementary food
Ph Eur: Pharmcopoeia Europeia
USP: The United States Pharmocopeia