PREVENTION OF FOOD ADULTERATION (VTH AMENDMENT) RULES, 2006

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 3rd July, 2006

***G.S.R. 398(E).-** Whereas a draft of certain rules further to amend the Prevention of Food Adulteration Rules, 1955, was published, as required by sub-section (i) of section 23 of the Prevention of Food Adulteration Act, 1954 (37 of 1954), at pages 1 to 59 in the notification of Government of India in the Ministry of Health and Family Welfare (Department of Health), number G.S.R. 37(E) dated the 20th January 2005, inviting objections and suggestions from all persons likely to be affected thereby till the expiry of sixty days from the date on which the copies of the Official Gazette containing the said notification, were made available to the public;

And whereas the copies of the said notification were made available to the public on 28th January 2005;

And whereas objections or suggestions received from the public within the specified period on the said draft rules have been considered by Central Government;

Now, therefore, in exercise of the powers conferred by section 23 of the said Act, the Central Government, after consultation with the Central Committee for Food Standards, hereby makes the following rules further to amend the Prevention of Food Adulteration Rules, 1955, namely:-

1. (1) These rules may be called the **Prevention of Food Adulteration (Vth Amendment) Rules, 2006.**

(2) They shall come into force after six months from the date of their publication in the Official Gazette.

2. In the Prevention of Food Adulteration Rules, 1955, (hereinafter referred to as the said rules), in rule 37B, -

(a) in sub rule (1), -

(i) in clause (d), for the words "spray or roller dried", the words "spray dried" shall be substituted;

(ii) in clause (f), at the end, the words "after opening use the contents within the period mentioned or the expiry date whichever is earlier", shall be added;

(iii) in clause (i), for the words "month and year before which it is to be consumed", the words "expiry date" shall be substituted.

(iv) after clause (j), the following clause shall be inserted, namely:-

"(k) the specific name of the food additives, if permitted, shall be declared in addition to appropriate class names.".

(b) in sub-rule (3), -

(i) for the words "low birth weight infant (less than 2500 gm)," the words "premature baby (born before 37 weeks)/low birth weight infant (less than 2500 gm)" shall be substituted;

(ii) in clause (a), for the words "low birth weight (infant?) (less than 2.5kg)", the words "PREMATURE BABY (BORN BEFORE 37 WEEKS)/LOW BIRTH WEIGHT (LESS THAN 2.5 KG)" shall be substituted;

(c) for sub-rule (5), the following sub-rules shall be substituted, namely:-

'(5) 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 -

---

**Published in the Gazette of India (extraordinary) Part-II, section 3, sub-section (i) vide G.S.R. 398(E), dated 3rd/4th July, 2006.*

FREE or LACTOSE and SUCROSE - FREE" in capital letters and statement "TO BE TAKEN UNDER MEDICAL ADVICE" and shall also bear the following statements, namely:-

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

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

(6) The container of infant milk substitute meant for infants with allergy to cow's/buffalo's milk protein or soy protein or label affixed thereto shall indicate conspicuously "HYPOALLERGENIC FORMULA" in capital letters and statement "TO BE TAKEN UNDER MEDICAL ADVICE.".

3. In Appendix B of the said rules,-

(a) for items A.11.02.13, A.11.02.13.01, A.11.02.13.02, A.11.02.13.03, the following shall be substituted, namely:-

"A.11.02.13 - Infant Milk Food means the product prepared by spray drying of the milk of cow or buffalo or a mixture thereof. The milk may be modified by the partial removal/substitution of different milk solids; carbohydrates, such as sucrose, dextrose and dextrins/maltodextrin, maltose and lactose; salts like phosphates and citrates; vitamins A, D, E, B Group, Vitamin C and other vitamins; and minerals like iron, copper, zinc and iodine. The source of Mineral Salts and Vitamin Compounds may be used from :-

1. **Calcium (Ca) -** Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic;
2. **Phosphorous (P) -** Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic, Magnesium phosphate dibasic, Potassium phosphate dibasic;
3. **Chloride (Cl) -** Calcium chloride, Choline chloride, Magnesium chloride, Manganese chloride, Sodium chloride, Sodium chloride iodized;
4. **Iron (Fe) -** Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate;
5. **Magnesium (Mg) -** Magnesium chloride, Magnesium oxide, Magnesium phosphate dibasic;
6. **Sodium (Na) -** Sodium bicarbonate, Sodium chloride, Sodium chloride iodized, Sodium citrate, Sodium phosphate monobasic;
7. **Potassium (K) -** Potassium phosphate dibasic;
8. **Copper (Cu) -** Cupric citrate, Cupric sulphate;
9. **Iodine (I) -** Potassium iodide, Sodium iodide;
10. **Zinc (Zn) -** Zinc sulphate;
11. **Manganese (Mn) -** Manganese chloride, Manganese sulphate;
12. **Vitamin A -** Retinyl acetate, Retinyl palmitate, Retinyl propionate;
13. **Provitamin A -** Beta-carotene;
14. **Vitamin D -** Vitamin D_2 - Ergocalciferol, Vitamin D_3 - Cholecalciferol, Cholecalciferol-cholesterol;
15. **Vitamin E -** d-alpha-tocopherol, dl-alpha-tocopherol, d-alpha-tocopheryl acetate, dl-alpha-tocopheryl acetate, d-alpha-tocopheryl succinate, dl-alpha-tocopheryl succinate;
16. **Thiamin (Vitamin B_1) -** Thiamin chloride hydrochloride, Thiamin mononitrate;
17. **Riboflavin (Vitamin B_2) -** Riboflavin, Riboflavin 5' -phosphate sodium;
18. **Niacin -** Nicotinamide, Nicotinic acid;
19. **Vitamin B_6** - Pyridoxine hydrochloride;
20. **Biotin (Vitamin H) -** d-biotin;
21. **Folacin -** Folic acid;
22. **Pantothenic acid -** Calcium pantothenate, Panthenol;
23. **Vitamin B_{12} -** Cyanocobalamin, Hydroxycobalamin;
24. **Vitamin K -** Phytylmenaquinone;

25. **Vitamin C -** Ascorbic acid, Sodium ascorbate, Calcium ascorbate, Ascorbyl-6-palmitate;
26. **Choline -** Choline bitartrate, Choline chloride;
27. **Inositol;**
28. **Selenium -** Sodium selenite.

The product shall be free of lumps and shall be uniform in appearance. It shall be free from starch and added antioxidants. It shall also be free from dirt, extraneous matter, preservatives and added colour and flavour and from any material which is harmful to human health. It shall not have rancid taste or musty odour. It shall not contain food additives. It shall conform to the following requirements, namely:-

1.	Moisture, per cent by weight (not more than)	4.5
2.	Total milk protein, per cent by weight (not less than)	12.0
3.	Milk fat, per cent by weight (not less than)	18.0
4.	Total ash, per cent by weight (not more than)	8.5
5.	Ash insoluble in dilute Hydrochloric acid, per cent by weight (not more than)	0.1
6.	Solubility: Solubility Index maximum Solubility per cent by weight (not less than)	 2.0 ml 98.5
7.	Vitamin A (as retinol) µg. per 100 g. (not less than)	350 µg
8.	Added Vitamin D (expressed as Cholecalciferol or Ergocalciferol) µg per 100g. (not less than)	4.5 µg
9.	Vitamin C, mg per 100 g. (not less than)	35 mg
10.	Thiamine, µg per 100 g. (not less than)	185 µg
11.	Riboflavin, µg per 100 g. (not less than)	275 µg
12.	Niacin, µg per 100 g. (not less than)	1160 µg
13.	Pyridoxine µg per 100 g. (not less than)	160 µg
14.	Folic acid, µg per 100 g. (not less than)	20 µg
15.	Pantothenic acid, mg per 100 g. (not less than)	1.4 mg
16.	Vitamin B_{12}, µg per 100 g. (not less than)	0.7 µg
17.	Choline, mg per 100 g. (not less than)	32 mg
18.	Vitamin K µg per 100 g. (not less than)	18 µg
19.	Biotin, µg per 100 g. (not less than)	7.0 µg
20.	Sodium mg per 100 g. (not less than)	90 mg
21.	Potassium, mg per 100 g. (not less than)	370 mg
22.	Chloride, mg per 100 g. (not less than)	250 mg
23.	Calcium, mg per 100 g. (not less than)	230 mg
24.	Phosphorous, mg per 100 g. (not less than)	115 mg
25.	Magnesium, mg per 100 g. (not less than)	22 mg
26.	Iron, mg per 100 g. (not less than)	5.0 mg
27.	Iodine, µg per 100 g. (not less than)	20 µg
28.	Copper, µg per 100 g. (not less than)	280 µg
29.	Zinc, mg per 100 g. (not less than) and not more than	2.5 mg 5.0 mg
30.	Manganese, µg per 100g. (not less than)	20 µg
31.	Selenium, µg per 100 g. (not less than)	14 µg
32.	Bacterial count, per g. (not more than)	10,000

33.	Coliform count absent in	0.1 gram
34.	Yeast and mould count absent in	0.1 gram
35.	Salmonella and Shigella absent in	25 gram
36.	E. coli absent in	0.1 gram
37.	Staphylococcus aureas absent in	0.1 gram

It shall be packed in hermetically sealed, clean and sound containers or in flexible pack made from film or combination or any of the substrate made of Board paper, polyethylene, polyester metallised film or in such a way to protect from deterioration.

It may be packed in nitrogen or a mixture of nitrogen and carbon dioxide.

A.11.02.13.01 - INFANT FORMULA means the product prepared by spray drying of the milk of cow or buffalo or mixture thereof. The milk may be modified by partial removal/substitution of milk fat with vegetable oils rich in polyunsaturated fatty acids and/or by different milk solids; carbohydrates such as sucrose, dextrose and dextrins/maltodextrin, maltose and lactose; salts such as phosphates and citrates; vitamins A, D, E, B and C group and other vitamins; minerals such as iron, copper, zinc and iodine and others. Vegetables oils rich in polyunsaturated fatty acids shall be added to partially substitute milk fat to an extent that the product shall contain a minimum of 12 per cent by weight of milk fat and a minimum of linoleate content of 1.398 g per 100 g. of the product.

The products shall also contain a minimum of 0.70 I.U. of vitamin E per 100 K. Calorie. It may contain in addition to the vitamins and minerals listed, other nutrients may be added when required in order to provide nutrients ordinarily found in human milk such as, -

1. Carotenes -Not less than 0.25 mg/L
2. Fluorine -Not less than 0.107 mg/L
3. Amino acids -Not less than 9 mg/L (only L forms of amino acids should be used)
4. Non-protein nitrogen -Not less than 173 mg/L
5. Nucleotides -Not less than 11.7 mg/L
6. Carnitine -Not less than 11.27 mg/L
7. Lactalbumin -Not less than 1.4 g/L
8. Lactoferrin -Not less than 0.27 g/L
9. Lysozyme -Not less than 0.8 g/L
10. Fucose -Not less than 1.3 g/L
11. Glucosamine -Not less than 0.7 g/L
12. Inositol -Not less than 0.39 g/L
13. Citric acid -Not less than 0.35 g/L
14. Cholesterol -Not less than 88 mg/L
15. Lipid Phosphorus -Not less than 7 mg/L
16. Prostaglandins -Not less than PGE 150 mg/L
    Not less than PGF 400 mg/L

When any of these nutrients is added, the amount of these added nutrients shall be declared on the label, which should be not less than mentioned. It may contain medium chain triglycerides, taurine, molybdenum and chromium.

The source of Mineral Salts and Vitamin Compounds may be used from:-

1. **Calcium (Ca) -** Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic;
2. **Phosphorous (P) -** Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic, Magnesium phosphate dibasic, Potassium phosphate dibasic;
3. **Chloride (Cl) -** Calcium chloride, Choline chloride, Magnesium chloride, Manganese chloride, Sodium chloride, Sodium chloride iodized;

4. **Iron (Fe) -** Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate;
5. **Magnesium (Mg) -** Magnesium chloride, Magnesium oxide, Magnesium phosphate dibasic;
6. **Sodium (Na) -** Sodium bicarbonate, Sodium chloride, Sodium chloride iodized, Sodium citrate, Sodium phosphate monobasic;
7. **Potassium (K) -** Potassium phosphate dibasic;
8. **Copper (Cu) -** Cupric citrate, Cupric sulphate;
9. **Iodine (I) -** Potassium iodide, Sodium iodide;
10. **Zinc (Zn) -** Zinc sulphate;
11. **Source of Manganese (Mn) -** Manganese chloride, Manganese sulphate.

Vitamins

1. **Vitamin A -** Retinyl acetate, Retinyl palmitate, Retinyl propionate;
2. **Provitamin A -** Beta-carotene;
3. **Vitamin D -** Vitamin D_2 - Ergocalciferol, Vitamin D_3 - Cholecalciferol, Cholecalciferol-cholesterol;
4. **Vitamin E -** d-alpha-tocopherol, dl-alpha-tocopherol, d-alpha-tocopheryl acetate, dl-alpha-tocopheryl acetate, d-alpha-tocopheryl succinate, dl-alpha-tocopheryl succinate;
5. **Thiamin (Vitamin B_1) -** Thiamin chloride hydrochloride, Thiamin mononitrate;
6. **Riboflavin (Vitamin B_2) -** Riboflavin, Riboflavin 5' -phosphate sodium;
7. **Niacin -** Nicotinamide, Nicotinic acid;
8. **Vitamin B_6** - Pyridoxine hydrochloride;
9. **Biotin (Vitamin H) -** d-biotin;
10. **Folacin -** Folic acid;
11. **Pantothenic acid -** Calcium pantothenate, Panthenol;
12. **Vitamin B_{12} -** Cyanocobalamin, Hydroxycobalamin;
13. **Vitamin K -** Phytylmenaquinone;
14. **Vitamin C -** Ascorbic acid, Sodium ascorbate, Calcium ascorbate, Ascorbyl-6-palmitate;
15. **Choline -** Choline bitartrate, Choline chloride;
16. **Inositol;**
17. **Selenium -** Sodium selenite.

The product shall be free of lumps and shall be uniform in appearance. It shall be free from added starch, added colour and added flavour. It shall not have rancid taste and musty odour.

It may contain food additive listed below, -

Food additives	**Maximum level in 100 ml of the ready-to-drink product**
pH-Adjusting Agents Sodium hydroxide} Sodium hydrogen carbonate} Sodium carbonate} Potassium hydroxide} Potassium hydrogen carbonate} Potassium carbonate} Calcium hydroxide}	Limited by good manufacturing practice and within the limits for sodium and potassium in all types of infant formulae
Sodium citrate} Potassium citrate} L(+) Lactic acid} Citric acid}	Limited by good manufacturing practice in all types of infant formulae

It shall conform to the following requirements, namely:-

1.	Moisture, per cent by weight (not more than)	4.5
2.	Total milk protein, per cent by weight (not less than) and not more than	10.0 16.0
3.	Total fat, percent by weight (not less than) Milk Fat, percent by weight (not less than) Linoleate per 100 gram (not less than)	18.0 12.0 1.398 g
4.	Total ash, per cent by weight (not more than)	8.5
5.	Ash insoluble in dilute Hydrochloric acid, per cent by weight (not more than)	0.1
6.	Solubility: (a) Solubility Index maximum (b) Solubility per cent by weight (not less than)	 2.0 ml 98.5
7.	Vitamin A (as retinol) µg. per 100 g. (not less than)	350 µg
8.	Added Vitamin D (expressed as Cholecalciferol or Ergocalciferol) µg. per 100g. (not less than)	4.5 µg
9.	Vitamin C, mg per 100 g. (not less than)	35 mg
10.	Thiamine, µg per 100 g. (not less than)	185 µg
11.	Riboflavin, µg per 100 g. (not less than)	275 µg
12.	Niacin, µg per 100 g. (not less than)	1160 µg
13.	Pyridoxine µg per 100 g. (not less than)	160 µg
14.	Folic acid, µg per 100 g. (not less than)	20 µg
15.	Pantothenic acid, mg per 100 g. (not less than)	1.4 mg
16.	Vitamin B_{12}, µg per 100 g. (not less than)	0.7 µg
17.	Choline, mg per 100 g. (not less than)	32 mg
18.	Vitamin K µg per 100 g. (not less than)	18 µg
19.	Biotin, µg per 100 g. (not less than)	7.0 µg
20.	Vitamin E (as α-tocopherol compounds) IU per 100g. (not less than)	3.15 IU
21.	Sodium mg per 100 g. (not less than)	90 mg
22.	Potassium, mg per 100 g. (not less than)	370 mg
23.	Chloride, mg per 100 g. (not less than)	250 mg
24.	Calcium, mg per 100 g. (not less than)	230 mg
25.	Phosphorous, mg per 100 g. (not less than)	115 mg
26.	Magnesium, mg per 100 g. (not less than)	22 mg
27.	Iron, mg per 100 g. (not less than)	5.0 mg
28.	Iodine, µg per 100 g. (not less than)	20 µg
29.	Copper, µg per 100 g. (not less than)	280 µg
30.	Zinc, mg per 100 g. (not less than) and not more than	2.5 mg 5.0 mg
31.	Manganese, µg per 100g. (not less than)	20 µg
32.	Selenium, µg per 100 g. (not less than)	14 µg
33.	Bacterial count, per g. (not more than)	10,000
34.	Coliform count absent in	0.1 gram
35.	Yeast and mould count absent in	0.1 gram
36.	Salmonella and Shigella absent in	25 gram
37.	E. coli absent in	0.1 gram
38.	Staphylococcus aureas absent in	0.1 gram

Premature/Low birth weight infant milk substitutes, -

Provided that the premature/low birth weight infant milk substitutes shall also meet the following requirement in addition to the requirements mentioned above:-

(i) Protein shall be 2.25 - 2.75 gram per 100 K. Cal/Joules

(ii) Mineral contents shall not be less than 0.5/gram per 100 K. Cal. The Calcium: Phosphorous ratio shall be 2:1. The Sodium, Potassium and Chloride combined together shall be less than 40 milli equivalent per Litre;

(iii) Whey:Casein ratio shall be 60:40. Essential amino acids should include taurine, cystine, tyrosine and histidine;

Lactose free infant milk substitute

Lactose and sucrose free infant milk substitute

Sucrose free infant milk substitute

Provided that the lactose free or lactose and sucrose free or sucrose free infant milk substitutes shall also meet the following requirement in addition to the requirements mentioned in the standard, provided that in these three products edible vegetable oil may be used in place of milk fat and lecithin may be used as an emulsifier:-

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

(ii) Lactose-free cow's/buffalo's milk-based formulas shall have carbohydrate as glucose, dextrose, dextrin/maltodextrin, maltose and sucrose.

Hypoallergenic infant milk substitutes

Provided that the Hypoallergenic infant milk substitutes shall also meet the following requirement in addition to the requirements mentioned in the standard:-

(i) Protein shall be hydrolyzed casein or;

(ii) 100% free amino acids as a protein source;

It shall be packed in hermetically sealed, clean and sound containers or in flexible pack made from film or combination or any of the substrate made of Board paper, polyethylene, polyester metallised film or in such a way to protect from deterioration. It shall be packed in nitrogen or a mixture of nitrogen and carbon dioxide.";

A.11.02.13.02 - MILK-CEREAL BASED COMPLEMENTARY FOOD Milk-cereal based complementary food commonly called as weaning food or supplementary food means foods based on milk, cereal and/or legumes (pulses), soyabean, millets, nuts and edible oil seeds, processed to low moisture content and so fragmented as to permit dilution with water, milk or other suitable medium.

Milk-cereal based complementary food is intended to supplement the diet of infants after the age of six months.

Milk cereal based complementary food are obtained from milk, variety of cereals, pulses, soyabean, millets, nuts and edible oil seeds after processing. It may contain edible vegetable oils, milk solid, various carbohydrates such as sucrose, dextrose, dextrins/maltodextrin, maltose and lactose, calcium salts; phosphates and citrates and other nutritionally significant minerals and vitamins. It shall contain a minimum of 10 per cent milk casein by weight of the product. It shall also contain minimum 5 per cent milk fat by weight. It shall not contain hydrogenated fats containing trans-fatty acids. It may contain fungal alfa amylase upto a maximum extent of 0.025 percent by weight, fruits and vegetables, egg or egg products. It may also include aminoacids such as lysine, methionine, taurine, carnitine etc.

The source of Vitamin Compounds and Mineral Salts may be used from,-

1. **Calcium (Ca) -** Calcium carbonate, Calcium phosphate tribasic, Calcium sulphate;
2. **Phosphorous (P) -** Calcium phosphate tribasic;
3. **Chloride (Cl) -** Sodium chloride;
4. **Iron (Fe) -** Hydrogen reduced iron, Electrolytic iron;

5. **Magnesium (Mg) -** Magnesium chloride, Magnesium oxide, Magnesium phosphate dibasic;
6. **Sodium (Na) -** Sodium chloride;
7. **Zinc (Zn) -** Zinc sulphate;

Vitamins

1. **Vitamin A -** Retinyl acetate, Retinyl palmitate, Retinyl propionate;
2. **Provitamin A -** Beta-carotene;
3. **Vitamin D -** Vitamin D_2 -Ergocalciferol, Vitamin D_3 -Cholecalciferol, Cholecalciferol-cholesterol;
4. **Vitamin E -** d-alpha-tocopherol, dl-alpha-tocopherol, d-alpha-tocopheryl acetate, dl-alpha-tocopheryl acetate, d-alpha-tocopheryl succinate, dl-alpha-tocopheryl succinate;
5. **Thiamin (Vitamin B_1) -** Thiamin chloride hydrochloride, Thiamin mononitrate;
6. **Riboflavin (Vitamin B_2) -**Riboflavin, Riboflavin 5' -phosphate sodium;
7. **Niacin** - Nicotinamide, Nicotinic acid;
8. **Vitamin B_6** - Pyridoxine hydrochloride;
9. **Biotin (Vitamin H)** - d-biotin;
10. **Folacin** - Folic acid;
11. **Pantothenic acid -** Calcium pantothenate, Panthenol;
12. **Vitamin B_{12} -** Cyanocobalamin, Hydroxycobalamin;
13. **Vitamin K** - Phytylmenaquinone;
14. **Vitamin C** - Ascorbic acid, Sodium ascorbate, Calcium ascorbate, Ascorbyl-6-palmitate;
15. **Choline -** Choline bitartrate, Choline chloride;
16. **Inositol**;
17. **Selenium**- Sodium selenite.

It shall be in the form of powder, small granules or flakes, free from lumps and shall be uniform in appearance.

It shall be free from dirt and extraneous matter and free from preservatives and added colour and flavour. It shall be free from any material, which is harmful to human health.

It may contain the following additives, -

Emulsifiers	**Maximum level in 100 g of product on a dry weight basis**
Lecithin	1.5 g.
Mono- and Diglycerides	1.5 g.
PH- Adjusting Agents	
Sodium hydrogen carbonate } Sodium carbonate } Sodium citrate } Potassium hydrogen carbonate } Potassium carbonate } Potassium citrate} Sodium hydroxide} Calcium hydroxide} Potassium hydroxide} L (+) Lactic acid } Citric acid}	Limited by good Manufacturing Practice within the limit for sodium.
Antioxidants Mixed tocopherols concentrate } ∞ - Tocopherol}	300 mg/Kg fat, singly or in combination
L-Ascorbyl palmitate }	200 mg/Kg fat

It shall conform to the following requirements, namely:-

1.	Moisture, per cent by weight (not more than)	5.0
2.	Total protein, per cent by weight (not less than)	12.0
3.	Fat, per cent by weight (not less than)	7.5
4.	Total Carbohydrate, per cent by weight (not less than)	55.0
5.	Total ash, per cent by weight (not more than)	5.0
6.	Ash insoluble in dilute Hydrochloric acid, per cent by weight (not more than)	0.1
7.	Crude fibre (on dry basis) per cent by weight (not more than)	0.1
8.	Vitamin A (as retinol) ug per 100 g. (not less than)	350 µg
9.	Added Vitamin D, ug per 100 g. (expressed as Cholecalciferol or Ergocalciferol (not less than)	5 µg
10.	Vitamin C, mg per 100 g. (not less than)	25 mg
11.	Thiamine (as hydrochloride), mg per 100 g. (not less than)	0.5 mg
12.	Riboflavin, mg per 100 g. (not less than)	0.3 mg
13.	Niacin, mg per 100 g. (not less than)	3.0 mg
14.	Folic acid ug per 100 g. (not less than)	20 µg
15.	Iron, mg per 100 g. (not less than)	5.0 mg
16.	Zinc mg per 100 g. (not less than) and not more than	2.5 mg 5.0 mg
17.	Bacterial count, per g. (not more than)	10,000
18.	Coliform count absent in	0.1 gram
19.	Yeast and mould count absent in	0.1 gram
20.	Salmonella and Shigella absent in	25 gram
21.	E. coli absent in	0.1 gram
22.	Staphylococcus aureas absent in	0.1 gram

It shall be packed in hermetically sealed, clean and sound containers or in flexible pack made from film or combination or any of the substrate made of Board paper, polyethylene, polyester metallised film or in such a way to protect from deterioration.

A.11.02.13.03 - PROCESSED CEREAL BASED COMPLEMENTARY FOOD commonly called as weaning food or supplementary food means foods based on cereal and/or legumes (pulses), soyabean, millets, nuts and edible oil seeds, processed to low moisture content and so fragmented as to permit dilution with water, milk or other suitable medium.

Processed cereal based complementary food are intended to supplement the diet of infants after the age of six months and up to the age of two years.

Processed cereal based complementary food are obtained from variety of cereals, pulses, soyabean, millets, nuts and edible oil seeds after processing. It shall contain milled cereal and legumes combined not less than 75 percent. Where the product is intended to be mixed with water before consumption, the minimum content of protein shall not be less than 15% on a dry weight basis and the quality of the protein shall not be less than 70% of that of casein. The sodium content of the products shall not exceed 100 mg/100 gram of the ready-to-eat product. Hydrogenated fats containing trans-fatty acids shall not be added to the products. It may also contain following ingredients: - protein concentrates, essential amino acids (only natural L forms of amino acids shall be used), iodized salt; milk and milk products; eggs; edible vegetable oils and fats; fruits and vegetables; various carbohydrates such as sucrose, dextrose, dextrin, maltose dextrin, lactose, honey, corn syrup; malt; potatoes.

The source of Vitamin Compounds and Mineral Salts may be used from,-

1. **Calcium (Ca) -** Calcium carbonate, Calcium phosphate tribasic, Calcium sulphate;
2. **Phosphorous (P) -** Calcium phosphate tribasic, Phosphoric acid;
3. **Chloride (Cl) -** Sodium chloride, Hydrochloric acid;
4. **Iron (Fe) -** Hydrogen reduced iron, Electrolytic iron;
5. **Sodium (Na) -** Sodium chloride;
6. **Zinc (Zn) -** Zinc acetate, Zinc chloride, Zinc oxide, Zinc sulphate;

Vitamins

1. **Vitamin A -** Retinyl acetate, Retinyl palmitate, Retinyl propionate;
2. **Provitamin A -** Beta-carotene;
3. **Vitamin D -** Vitamin D_2 - Ergocalciferol, Vitamin D_3 - Cholecalciferol, Cholecalciferol-cholesterol;
4. **Vitamin E -** d-alpha-tocopherol, dl-alpha-tocopherol, d-alpha-tocopheryl acetate, dl-alpha-tocopheryl acetate, d-alpha-tocopheryl succinate, dl-alpha-tocopheryl succinate;
5. **Thiamin (Vitamin B_1) -** Thiamin chloride hydrochloride, Thiamin mononitrate;
6. **Riboflavin (Vitamin B_2) -** Riboflavin, Riboflavin 5' -phosphate sodium;
7. **Niacin** - Nicotinamide, Nicotinic acid;
8. **Vitamin B_6 -** Pyridoxine hydrochloride;
9. **Biotin (Vitamin H) -** d-biotin;
10. **Folacin** - Folic acid;
11. **Pantothenic acid -** Calcium pantothenate, Panthenol;
12. **Vitamin B_{12} -** Cyanocobalamin, Hydroxycobalamin;
13. **Vitamin K** - Phytylmenaquinone;
14. **Vitamin C -** Ascorbic acid, Sodium ascorbate, Calcium ascorbate, Ascorbyl-6-palmitate;
15. **Choline -** Choline bitartrate, Choline chloride;
16. **Inositol;**
17. **Selenium-** Sodium selenite.

It shall be in the form of powder, small granules or flakes, free from lumps and shall be uniform in appearance.

All ingredients, including optional ingredients, shall be clean, safe, suitable and of good quality. It shall be free from preservatives, added colour and flavour.

It may contain the following food additives:-

Name of the food additives	**Maximum level in 100 g of product, on a dry weight basis**
Emulsifiers	
Lecithin	1.5 gram
Mono-and diglycerides	1.5 gram
pH Adjusting Agents	
Sodium hydrogen carbonate	Limited by good manufacturing practice and within the limits for sodium
Potassium hydrogen carbonate }	Limited by good manufacturing practice
Calcium carbonate }	
L(+) lactic acid	1.5 gram
Citric acid	2.5 gram

Antioxidants Mixed tocopherols concentrate } Alpha-tocopherol }	300 mg/kg fat, singly or in combination
L-Ascorbyl palmitate	200 mg/kg fat
L-Ascorbic acid and its sodium and potassium salts	50 mg, expressed as ascorbic acid and within the limits for sodium
Enzymes Malt carbohydrates	Limited by good manufacturing practice
Leavening Agents Ammonium carbonate } Ammonium hydrogen carbonate}	Limited by good manufacturing practice

It shall also conform to the following requirements, namely:-

1.	Moisture, per cent by weight (not more than)	4.0
2.	Total protein, per cent by weight (not less than)	15.0
3.	Total Carbohydrate, per cent by weight (not less than)	55.0
4.	Total ash, per cent by weight (not more than)	5.0
5.	Ash insoluble in dilute Hydrochloric acid, per cent by weight (not more than)	0.1
6.	Crude fibre (on dry basis) per cent by weight (not more than)	1.0
7.	Vitamin A (as retinol) ug per 100 g. (not less than)	350 µg
8.	Added Vitamin D, ug per 100 g. (expressed as Cholecalciferol or Ergocalciferol (not less than)	5 µg
9.	Vitamin C, mg per 100 g. (not less than)	25 mg
10.	Thiamine (as hydrochloride), mg per 100 g. (not less than)	0.5 mg
11.	Riboflavin, mg per 100 g. (not less than)	0.3 mg
12.	Niacin, mg per 100 g. (not less than)	3.0 mg
13.	Folic acid ug per 100 g. (not less than)	20.0 µg
14.	Iron, mg per 100 g. (not less than)	5.0 mg
15.	Zinc mg per 100 g. (not less than) and not more than	2.5 mg 5.0 mg
16.	Bacterial count, per g. (not more than)	10,000
17.	Coliform count absent in	0.1 gram
18.	Yeast and mould count absent in	0.1 gram
19.	Salmonella and Shigella absent in	25 gram
20.	E. coli absent in	0.1 gram
21.	Staphylococcus aureas absent in	0.1 gram

It shall be packed in hermetically sealed clean and sound containers or in flexible pack made from film or combination of any or the substrate made of board paper, polyethylene, polyester, metalised film or aluminum foil in such a way to protect from deterioration.";

A. 11.02.13.04 - Follow-Up Formula-Complementary Food" means the product prepared by spray drying of the milk of cow or buffalos or mixture thereof. It may contain vegetable protein. Follow-up formula based on milk shall be prepared from ingredients mentioned below except that a minimum of 3 gram per 100 available Calories (or 0.7 gram per 100 kilojoules) of protein shall be derived from whole or skimmed milk as such, or with minor modification that does not

substantially impair the vitamin or mineral content of the milk and which represents a minimum of 90% of the total portein.

Follow-up formula for use as a liquid part of the complementary diet for infants **after the age of six months and up to the age of two years** when prepared in accordance with the instructions for use, 100 ml of the ready-for-consumption product shall provide not less than 60 kcal (or 250 kJ) and not more than 85 kcal (or 355 kJ).

Follow-up formula shall contain the following nutrients indicated below,

(1) Protein - Not less than 3.0 gram per 100 available calories (or 0.7 gram per 100 available kilojoules)

Not more than 5.5 g per 100 available calories (or 1.3 g per 100 available kilojoules).

(Protein shall be of nutritional quality equivalent to that of casein or a greater quantity of other protein in inverse proportion to its nutritional quality. The qualtiy of the protein shall not be less than 85% of that of casein).

Esssential amino acids may be added to follow-up formula to improve its nutritional value. Only L forms of amino acids shall be used.

(2) Fat - Not less than 4 g per 100 Calories (0.93 gram per 100 available kilojoules)

Not more than 6 gram per 100 calories (1.4 gram per 100 available kilojoules)

Linoleic acid - Not less than 310 mg

(in the form per 100 Calories (or 74.09 mg per 100 available of glyceride) kilojoules).

The products shall contain nutritionally available carbohydrates suitable for the feeding of the older infant any young child in such quantities as to adjust the product to the energy density in accordance with the requirements given above.

It may also contain other nutrients when required to ensure that the product is suitable to form part of a mixed feeding scheme intended for use after six months of age. When any of these nutrients is added, the food shall contain not less than Recommended Dietary Allowances (RDA) amounts of these nutrients.

The source of Mineral Salts and Vitamin Compounds may be used from, -

1. **Calcium (Ca)-**Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic;
2. **Phosphorous (P)-** Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic, Magnesium phosphate dibasic, Potassium phosphate dibasic;
3. **Chloride (Cl)-**Calcium chloride, Choline chloride, Magnesium chloride, Manganese chloride, Sodium chloride, Sodium chloride iodized;
4. **Iron (Fe)-** Ferrous citrate Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate;
5. Magnesium **(Mg)-** Magnesium chloride, Magnesium oxide, Magnesium phosphate dibasic;
6. **Sodium (Na)-** Sodium bicarbonate, Sodium chloride, Sodium chloride iodized, Sodium citrate, Sodium phosphate monobasic;
7. **Potassium (K)-** Potassium phosphate dibasic;
8. **Copper (Cu)-** Cupric citrate, Cupric sulphate;
9. **Iodine (I)**-Potassium iodide, Sodium iodide;
10. **Zinc (Zn)-** Zinc sulphate;
11. **Source of Manganese (Mn)-** Manganese chloride, Manganese sulphate.

Vitamins

1. **Vitamin A -** Retinyl acetate, Retinyl palmitate, Retinyl propionate;
2. **Provitamin A -** Beta-carotene;

3. **Vitamin D -** Vitamin D_2 - Ergocalciferol, Vitamin D_3 - Cholecalciferol, Cholecalciferol-cholesterol;
4. **Vitamin E -** d-alpha-tocopherol, dl-alpha-tocopherol, d-alpha-tocopheryl acetate, dl-alpha-tocopheryl acetate, d-alpha-tocopheryl succinate, dl-alpha-tocopheryl succinate;
5. **Thiamin (Vitamin B_1) -** Thiamin chloride hydrochloride, Thiamin mononitrate;
6. **Riboflavin (Vitamin B_2) -** Riboflavin, Riboflavin 5' -phosphate sodium;
7. **Niacin**-Nicotinamide, Nicotinic acid;
8. **Vitamin B_6 -** Pyridoxine hydrochloride;
9. **Biotin (Vitamin H) -** d-biotin;
10. **Folacin** - Folic acid;
11. **Pantothenic acid -** Calcium pantothenate, Panthenol;
12. **Vitamin B_{12} -** Cyanocobalamin, Hydroxycobalamin;
13. **Vitamin K** - Phytylmenaquinone;
14. **Vitamin C -** Ascorbic acid, Sodium ascorbate, Calcium ascorbate, Ascorbyl-6-palmitate;
15. **Choline -** Choline bitartrate, Choline chloride;
16. **Inositol;**
17. **Selenium -** Sodium selenite.

The product shall be free of lumps and shall be uniform in appearance. It shall be free from added starch and added colour and flavour. It shall not have rancid taste and musty odour.

It may contain the following additives, -

	Maximum Level in 100 ml of Product Ready-for-Consumption
PH-Adjusting Agents Sodium hydrogen carbonate } Sodium carbonate } Sodium citrate} Potassium hydrogen carbonate} Potassium carbonate } Potassium citrate} Sodium hydroxide} Calcium hydorxide } Potassium hydroxide} L(+) Lactic acid } Citric acid}	Limited by good Manufacturing Practice within the limit for sodium
Antioxidants Mixed tocopherols concentrate } ∞ - Tocopherol } L-Ascorbyl palmitate }	3 mg singly or in combination 5 mg singly or in combination.

It shall also conform to the following requirements,-

S. No.	**Characteristics**	**Requirements**
1.	Moisture, per cent by weight (not more than)	4.5
2.	Total milk protein, per cent by weight (not less than) and (not more than)	13.5 24.75
3.	Total fat, per cent by weight (not less than) and (not more than) Linoleate (not less than)	18.0 27.0 1.398 gm
4.	Total ash, per cent by weight (not more than)	8.5

5.	Ash insoluble in dilute Hydrochloric acid, per cent by weight (not more than)	0.1
6.	Solubility: Solubility Index maximum Solubility per cent by weight (not less than)	 2.0 ml. 98.5
7.	Vitamin A (as retinol) ug per 100 g. (not less than)	75 µg
8.	Added Vitamin D (expressed as Cholecalciferol or Ergocalciferol) µg per 100 g. (not less than)	4.5 µg
9.	Vitamin C, mg per 100 g. (not less than)	36 mg
10.	Thiamin, mcg per 100 g. (not less than)	180 µg
11.	Riboflavin, µg per 100 g. (not less than)	270 µg
12.	Niacin, µg per 100 g. (not less than)	1125 µg
13.	Pyridoxine µg per 100 g. (not less than)	202.50 µg
14.	Folic acid, µg per 100 g. (not less than)	20.0 µg
15.	Pantothenic acid, mg per 100 g. (not less than)	1.35 mg
16.	Vitamin B12, µg per 100 g. (not less than)	0.675 µg
17.	Choline, mg per 100 g. (not less than)	32 mg
18.	Vitamin K µg per 100 g. (not less than)	18 µg
19.	Biotin, µg per 100 g. (not less than)	6.75 µg
20.	Vitamin E (as α- tocopherol compounds) I.U. per 100g (not less than)	3.15 IU
21.	Sodium, mg per 100 g. (not less than)	90 mg
22.	Potassium, mg per 100 g. (not less than)	360 mg
23.	Chloride, mg per 100 g. (not less than)	247.50 mg
24.	Calcium, mg per 100 g. (not less than)	405 mg
25.	Phosphorous, mg per 100 g. (not less than)	270 mg
26.	Magnesium, mg per 100 g. (not less than)	27 mg
27.	Iron, mg per 100 g. (not less than)	5 mg
28.	Iodine, µg per 100 g. (not less than)	22.50 µg
29.	Copper, µg per 100 g. (not less than)	280 µg
30.	Zinc, mg per 100 g. (not less than) and (not more than)	2.5 mg 5.0 mg
31.	Manganese, µg per 100 g. (not less than)	20 µg
32.	Selenium, µg per 100 g. (not less than)	14 µg
33.	Bacterial count, per g. (not more than)	10,000
34.	Coliform count absent in	0.1 gram
35.	Yeast and mould count absent in	0.1 gram
36.	Salmonella and Shigella absent in	25 gram
37.	E. coli absent in	0.1 gram
38.	Staphylococcus aureas absent in	0.1 gram

It shall be packed in hermitically sealed, clean and sound containers or in flexible pack made from film or combination or any of the substrate made of Board paper, polyethylene, polyester metallised film or in such a way to protect from deterioration. It shall be packed in nitrogen or a mixture of nitrogen and carbon dioxide.".

[No. P. 15014/7/2003-PH(Food)]

RITA TEAOTIA, Jt. Secy.
