

Notice calling for suggestions, views, comments etc from stakeholders on the draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2018 relating to standards of formulated supplements for children (draft notified as complementary foods for older infants and young children).

F.No. Stds/03/Notification (CFOI&YC)/FSSAI-2017

1. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in regulation 2.4, in sub-regulation 2.4.11, after clause 3 relating to “Malt extract”, the following clause shall be inserted, namely,-

“4. Formulated supplements for children

(1) Scope: This standard specifies requirements of formulated supplements for children of age above 24 months till 36 months.

(2)Description: Formulated supplements for children are shall be of appropriate nutritional quality to provide additional energy and nutrients to complement the family foods derived from the local diet by providing those nutrients that are either lacking or are present in insufficient quantities. These foods may be presented in any other age suitable food format.

(3) Suitable raw materials and ingredients:

(i) Basic raw materials and ingredients permitted to be used include:-

(a) Cereals: All milled cereals suitable for human consumption processed in such a way as to reduce the fibre content, when necessary. Such cereals processed in a way to decrease, and, if possible to eliminate the anti-nutrients such as phytates, tannins and other phenolic materials, lectins, trypsins and chymo-trypsin inhibitors which can lower the protein quality and digestibility, amino acid bioavailability and mineral absorption shall be permitted. Appropriate enzymes for decreasing the fibre content and anti-nutrients may be used during such processing. Cereals as a source should mainly contain carbohydrates and significant quantity (8-12%) of protein.

(b) Legumes and Pulses: Legumes and pulses such as chick peas, cow peas, lentils, peas, green gram, kidney beans, soya beans containing at least 20% protein on dry basis. Legumes and pulses provide lysine that is deficient in cereals but deficient in L-methionine which may be added.

Legumes and pulses must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present such as phytates, lectins (haemagglutinins), trypsin and chemo-trypsin inhibitors. Soya when used must be ensured that it contains low levels of phytoestrogens. [lectins may be reduced by moist heat treatment; trypsin inhibitor activity by heating to high temperature or prolonged

boiling; phytates may be reduced enzymatically or by soaking; phytoestrogens by fermentation]. Field beans and faba beans shall not be used due to favism.

(c) Oil seed flours and oil seed protein products: Flours, protein concentrates and protein isolates of oil seeds with reduced anti-nutritional factors and undesirable toxic substances such as trypsins and chymotrypsin inhibitors, gossypol and urease activity. Following oil seeds depending on local conditions and requirements may be used;

- Soyabeans: dehulled flour, (full fat and defatted) protein concentrate, protein isolate
- Ground nut: paste, protein isolate
- Sesame seeds: whole ground and defatted flour
- Sunflower seed: defatted flour
- Low erucic acid rape seed: full fat flour

Defatted oil seed flours and protein isolates, if produced and appropriately processed for human Consumption, can be used as a good source of protein (47-95%).

(d) Animal source foods: Animal source foods such as meat, fish, poultry and eggs are nutrient dense and source of high quality protein and micronutrients. It may also contain protein concentrates derived from these sources.

(e) Fats and oils: Fats and oils may be added in adequate quantities for the purpose of increasing the energy density of the product. It shall not contain partially hydrogenated fats.

(f) Fruits and vegetables: Fruits and vegetables as a good source of micronutrients, when technologically feasible.

(g) Milk and milk products: Foods such as milk and milk products are nutrient dense and source of high quality protein and micronutrients. It may also contain protein concentrates derived from these sources.

(ii) Other ingredients: Other ingredients including those listed below may be used to improve the nutritional quality:

(a) Digestible carbohydrates to increase energy density of foods.

(b) Protein isolates, concentrates and hydrolysates.

(c) Probiotic ingredient(s) and prebiotic ingredient(s) as provided under schedule VII and schedule VIII, respectively, 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 along with other requirements laid down under the said regulations.

(d) Vitamins, minerals and other nutrients: Following vitamins, minerals and other nutrients may be added to improve the micronutrient levels of the product at the levels as shown in the table:

1	Vitamin A (as retinol), µg per 100 g	Not less than 200 Not more than 400
2	Vitamin D (expressed as cholecalciferol or ergocalciferol),µg per 100g	Not less than 5 Not more than 10
3	Vitamin C, mg per 100 g	Not less than 20 Not more than 40
4	Thiamine, µg per 100 g	Not less than 250 Not more than 500
5	Riboflavin, µgper 100g	Not less than 300 Not more than 600
6	Niacin, mg per 100 g	Not less than 4 Not more than 8
7	Pyridoxine,µg per 100 g	Not less than 450 Not more than 900
8	Folic Acid, µg per 100 g ¹	Not less than 24 Not more than 48
9	Pantothenic acid, mg per 100 g	Not less than 1.0 Not more than 2.0
10	Vitamin B ₁₂ , µg per 100 g	Not less than 0.25 Not more than 0.5
11	Choline, mg per 100 g	Not less than 32
13	Vitamin K, µg per 100 g	Not less than 7.50 Not more than 15
14	Biotin, µg per 100 g	Not less than 4 Not more than 8
15	Vitamin E (as L- tocopherols), mg per 100g	Not less than 2.5 Not more than 5
16	Sodium, mg per 100 g	Not less than 90 Not more than 300
17	Potassium, mg per 100 g	Not less than 300 Not more than 900
18	Chloride, mg per 100 g	Not less than 250 Not more than 800
19	Calcium, mg per 100 g	Not less than 300 Not more than 600
20	Phosphorus, mg per 100 g	Not less than 225 Not more than 450
21	Magnesium, mg per 100g	Not less than 25 Not more than 50
22	Iron, mg per 100 g	Not less than 4.5 Not more than 9
23	Iodine, µ g per 100 g	Not less than 45 Not more than 90

24	Copper, µg per 100 g	Not less than 170 Not more than 340
25	Zinc, mg per 100g	Not less than 2.5 Not more than 5.0
26	Manganese, mg per 100 g	Not less than 0.6 Not more than 1.2
28	Selenium, µg per 100 g	Not less than 8.5 Not more than 17
29	Inositol, g per litre*	Not more than 0.40
30	a. Docosahexaenoic acid, mg per 100 g b Arachidonic acid and Eicosapentaenoic acid	Not less than 50 Same as DHA
31	Taurine, mg per 100 g	Not more than 60
32	Essential amino acids, mg per litre*	Not less than 9

* When prepared in accordance with instructions for use; ¹1 microgram DFE = 0.6 microgram folic acid.

(±5.0% of the values due to analytical variations from the quantities of these ingredients declared on the label of the product shall be permitted).

Vitamins, minerals, amino acids and other compounds may be chosen from sub-regulation 2.1.19 related to 'Foods for Infant Nutrition' of these regulations.

(4) Essential requirements:

- i) Energy density shall be at least 4 kilo calories per gram on dry basis;
- ii) Protein digestibility corrected amino acid score (PDCAAS) shall not be less than 70% of the WHO amino acid pattern for the children from 2 to 5 years. Protein shall be min 15% with Protein Efficiency Ratio (PER) of 2.0 or minimum 20% with PER of 1.75.
- iii) Moisture (per cent by weight) : Max 8.0;
- iv) Fat (per cent by weight): Max 7.5;
- v) Total ash (per cent by weight): Max 7.5;
- vi) The product shall conform to the microbiological requirements of 'Follow up formula' given in Appendix B of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

(5) Food additives: The following food additives may be used in the preparation of formulated supplements for children in 100g of the product ready for consumption prepared following Manufacturer's instruction, unless otherwise indicated.

Carry-over of food Additives into foods shall be in accordance with clause 3.1.1.(10) of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

INS No.	Additive	Maximum level
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Emulsifiers			
322	Lecithins	1500 mg	
471	Mono- and diglycerides	500 mg Singly or in combination	
472a	Acetic and fatty acid esters of glycerol		
472b	Lactic and fatty acid esters of glycerol		
472c	Citric and fatty acid esters of glycerol		
Acidity Regulators			
500 ii	Sodium hydrogen carbonate	GMP	
501 ii	Potassium hydrogen carbonate		
170 i	Calcium carbonate		
270	L(+) Lactic acid		
330	Citric acid		
260	Acetic acid		
261	Potassium acetates		
262 i	Sodium acetate		
263	Calcium acetate		
296	Malic acid (DL) – L(+)-form only		
325	Sodium lactate (solution) – L(+)-form only		
326	Potassium lactate (solution) – L(+)-form only		
327	Calcium lactate – L(+)-form only		
331i	Monosodium citrate		
331ii	Trisodium citrate		
332i	Monopotassium citrate		
332ii	Tripotassium citrate		
333	Calcium citrate		
507	Hydrochloric acid		
524	Sodium hydroxide		
525	Potassium hydroxide		
526	Calcium hydroxide		
575	Glucono delta-lactone		
334	L(+)-Tartaric acid – L(+)form only		500 mg Singly or in combination
335 i	Monosodium tartrate		
335 ii	Disodium tartrate		
336 i	Monopotassium tartrate –L(+)-form only		Tartrates as residue in biscuits and rusks
336 ii	Dipotassium tartrate – L(+)-form only		
337	Potassium sodium L(+)-tartrate L(+)-form only	Only for pH adjustment 440 mg	
338	Orthophosphoric acid		
339 i	Monosodium orthophosphate		
339 ii	Disodium orthophosphate		
339 iii	Trisodium orthophosphate		
340 i	Monopotassium orthophosphate		
340 ii	Dipotassium orthophosphate		

340 iii	Tripotassium orthophosphate	Singly or in combination as phosphorous
341 i	Monocalcium orthophosphate	
341 ii	Dicalcium orthophosphate	
341 iii	Tricalcium orthophosphate	
Antioxidants		
306	Mixed tocopherols concentrate	300 mg/kg fat or oil basis, Singly or in combination
307	Alpha-tocopherol	
304	L-Ascorbylpalmitate	200 mg/kg fat
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 Agents		
503 i	Ammonium carbonate	Limited by GMP
503 ii	Ammonium hydrogen carbonate	
500 i	Sodium carbonate	
500 ii	Sodium hydrogen carbonate	
Thickeners		
410	Carob bean gum	1000 mg singly or in combination
412	Guar gum	
414	Gum arabic	
415	Xanthan gum	2000 mg in gluten-free cereal-based foods
440	Pectins (Amidated and Non- Amidated)	
1404	Oxidized starch	5000 mg Singly or in combination
1410	Monostarch phosphate	
1412	Distarch phosphate	
1413	Phosphateddistarch phosphate	
1414	Acetylated distarch phosphate	
1422	Acetylated distarchadipate	
1420	Starch acetate esterified with acetic anhydride	
1450	Starch sodium octenyl succinate	
1451	Acetylated oxidized starch	
Anticaking Agents		
551	Silicon dioxide (amorphous)	200 mg for dry cereals only
Packaging Gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP
Flavours		
	Natural fruit extracts	GMP
	Vanilla extract	GMP
	Ethyl vanillin	7 mg

	Vanillin	7mg
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(6) The product and its components shall not have been treated by ionizing radiation.

(7) Contaminants, Toxins and Residues: (i) The product shall conform to the limits of contaminants as Specified in Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

(ii) The products shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredients do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

(iii) The product shall be free from residues of hormones, antibiotics as determined by means of agreed methods of analysis and practically free from other contaminants, especially pharmacologically active substances.

(8) Food Hygiene: The product shall be prepared and handled in accordance with Schedule 4 of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

(9) Packaging and Labelling:

(i) The food 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.

(ii) The product shall be labelled in accordance with the Food Safety and Standards (Packaging and Labelling) Regulations, 2011 and the specific labelling requirements provided in these regulations.

(iii) The name of the food to be declared on the label shall indicate that the food is a formulated supplement for children. Provided that these products shall not be presented as 'Energy food' or 'Health food'. Label of this food shall not refer to malnourished children.

(iv) The label should clearly indicate the major sources of protein and product is recommended for children age above 24 months till 36 months.

(v) The label shall also declare information relating to allergen.

(vi) Instructions for use:

(a) Directions as to the preparation and use of the food shall be given; preferably accompanied by graphical presentations.

(b) In the case that addition of water is needed, the directions for the preparation shall include a precise statement that:

(i) where the food contains non-heat-processed basic ingredients, the food must be adequately boiled in a prescribed amount of water;

(ii) where the food contains heat-processed basic ingredients:

(a) the food requires boiling, or

(b) can be mixed with boiled water that has been cooled.

(vi) Formulated supplements for Children foods to which fats, sugars or other digestible carbohydrates shall be added during preparation, the instructions for use shall identify appropriate sources and indicate the amounts of the ingredients to be added. In such situations, fats and oils with an appropriate essential fatty acid ratio shall be recommended.

(vii) Directions for use shall include a statement that only an amount of food sufficient for one feeding occasion shall be prepared at one time. Foods not consumed during the feeding occasion shall be discarded, unless consumed within a period as recommended by the manufacturer under the instructions for use.

(viii) The label shall also include a statement that formulated supplements for children are to be consumed to complement family foods and breast milk/breast milk substitutes.

(10) Method of sampling and analysis: Method of sampling and analysis shall be as per the Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011 and manuals published by the Food Authority.