Notice Calling for suggestions, views, comments etc from WTO- SPS Committee members within a period of 60 days on the draft notification related to standards of Complementary Foods for Older Infants and Young Children.

F. No. Stds/03/Notification (CFOI&YI)/ FSSAI-2017.- 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. Complementary Foods for Older Infants and Young Children

This standard specifies requirements for complimentary foods for older infants and young children.

(1) Description:

(i) Complementary foods for older infants and young children means foods those are suitable for use during and beyond complementary feeding period. These foods are specially formulated with 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.

Complementary feeding period means the period when the older infants transition from exclusive feeding of breast milk and/or breast milk substitutes to eating the family diet.

(ii) Older infants mean infants of age more than 18 months to 24 months.

(iii) Young children mean children of age more than 24 months to 5 years.

(2) 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 prescribed 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 (haemagglutenins), trypsin and chemo-trypsin inhibitors. Soya when used, must be ensured that it contains low levels of phytoerstroges [lectins may be reduced by moist heat treatment; tryspsin 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 should 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: defatted 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 food source of protein (50-95%).

(d) Animal source foods: Animal source foods such as meat, fish, poultry and eggs are nutrient dense and source of high quality protein and nutrients.

(e) Fats and oils: Fats and oils which are energy dense may be added in adequate quantities. Use of partially hydrogenated fats is prohibited.

(f) Fruits and vegetables: as a source of micronutrients.

(g) Milk and milk products.

(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) Vitamins and minerals: Following vitamins and minerals may be added to improve the micronutrient levels of the product at the levels (calculated at minimum 50% RDA and maximum 1 RDA) 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 100 g	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, µg per 100 g	Not less than 300 Not more than 600
6	Niacin, µg per 100 g	Not less than 4,000 Not more than 8,000
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 20 Not more than 40
9	Pantothenic acid, mg per 100 g	Not less than1.0

		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 7.5 Not more than 50.0
15	Vitamin E (as L- tocopherols), mg per 100 g	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, µg per 100 g	Not less than 0.6 Not more than 1.2
28	Selenium, µg per 100 g	Not less than 0.85 Not more than 17
29	Inositol, g per litre*	Not more than 0.40
30	a. Docosa hexaenoic acid per 100 g b Arachidonic acid :	Not less than 50

	c. Eicosapentaenoic acid	Not more than 100
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.

(±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 Schedule 1(a), 1(b) and 1(c) respectively from Infant Food Regulations.

[1]For converting folic acid to dietary folate equivalent (DFE) use the conversion factor of 1DEF µg = 0.5 µg folic acid

** With a iron bioavailability factor of 5%

*** With a zinc bioavailability factor of 25%

(4) Essential requirements:

(i) Energy density should be at least 4 kilo calories per gram on dry basis

(ii) Protein digestibility corrected amino acid score (PDCAAS) should 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 % by weight max 8.0

(iv) Fat % by weight max 7.5

(v) Total ash % by weight max 7.5

(vi) Bacterial count, per gram not more than 10,000 colonies (TPC)

(vii) Coliform count absent in 0.1 gram

(viii) E. coli count absent in 0.1 gram

(ix) Yeast and mould count absent in 0.1 gram

(x) Staphylococcus aureus absent in 0.1 gram

(xi) Bacillus cereus absent in 0.1 gram

(xii) Salmonella and Shigella absent in 0.1 gram

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

INS	**Additive**	**Maximum Level**
Thickening agent		
412	Guar gum	0.1 g
410	Locust bean gum (carob bean gum)	0.5 g singly or in combination
1412	Distarch phosphate	
1414	Acetylated distarch phosphate	
1413	Phosphateddistarch phosphate	
1414	Acetylated distarchadipate	2.5 g in hydrolyzed protein and /or Amino acid based product
407	Carrageenan	0.03 g in milk and soy based product
440	Pectins	1 g
Emulsifiers		
322	Lecithin	0.5 g
471	Mono- and diglycerides	0.4 g
pH adjusting agents		
500ii	Sodium hydrogen carbonate	limited by GMP within the limits for sodium in section (3)(ii)(b)
500i	Sodium carbonate	
331i	Sodium citrate	
501ii	Potassium hydrogen carbonate	
501i	Potassium carbonate	
332i	Potassium citrate	
525	Sodium hydroxide	
525	Potassium hydroxide	
526	Calcium hydroxide	
270	L(+) lactic acid L(+) lactic acid producing cultures	
Antioxidants		
306	Mixed tocopherol concentrate	3 g 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

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

(7) Packaging and Labelling:

(i) The food shall be packed in hermetically sealed, clean and sound containers or in flexible pack made from film or combination of any other substrate made of board, paper, polyethylene, polyester, metallized film or in such a way to protect from deterioration. It may be packed with nitrogen or mixture of nitrogen and carbon dioxide flushing and filling during packing to remove atmosphere of oxygen within the pack.

(ii) The product shall be labelled in accordance with regulations 2.2, 2.3 and 2.4 of Food Safety and Standards (Packaging and Labelling) Regulations, 2011.

(iii) Products under these regulations shall also comply with labelling requirements prescribed in "Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 as amended in 2003 (IMS Act)."