

Food Safety and Standards Infant nutrition Regulations 2020

PFNDAI Webinar, 10th March 2021

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

NOTIFICATION

New Delhi, the 4th December, 2020

F. No. Stds/03/Notification (IFR)/ FSSAI-2017.—Whereas the draft of the Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2019 were published as required by section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), vide notification of the Food Safety and Standards Authority of India number F. No. Stds/03/Notification (IFR)/ FSSAI-2017, dated the 1st May, 2019, in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of thirty 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 Gazette were made available to the public on the 14th May, 2019;

- 1. Short title and commencement:** (1) These regulations may be called the Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020.
- (2) They shall come into force on the date of their publication in the Official Gazette and Food Business Operator shall comply with all the provisions of these regulations by 1st July, 2021.

Salient features

- Clear distinction between products meant for infant nutrition
- Stringent nutrient ranges
- Additives alignment and additional ingredients
- Labelling requirements
- New sections- FSMP for infants including LBW, IEM

Clear distinction between products meant for infant nutrition

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| (c) “Food for infants based on traditional food ingredients” are products known to be prepared traditionally at home for feeding infants, but processed and provided in packaged forms, after six months up to twenty-four months of age; | New category |
| (d) “Food for special medical purpose intended for infants” means a substitute for human milk or formula that is specially manufactured to meet the special nutritional requirements of infants from birth to twenty-four months with specific disorders, diseases or medical conditions; | New category |
| (e) “Follow-up formula” means a food for infants after six months up to twenty four months of age, which is intended for use as a liquid part of the complementary diet for infants when prepared in accordance with instructions for use; | 6-24 months |
| (f) “Infant Food” shall have the meaning assigned to it in clause (x) of sub-section (1) of Section 3 of the Act; | |
| (g) “Infant Milk substitute” shall have the meaning assigned to it in clause (x) of sub-section (1) of Section 3 of the Act; | |
| (h) “Infant formula” means a breast milk substitute product based on milk of cow or buffalo or other milch animals as specified under the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 or mixture thereof and other ingredients which have been proven to be suitable for infant feeding, to meet the nutritional requirements of infant during the first six months; | 0-6 months |
| (i) “Milk cereal based complementary food” means the food for infants after 6 months up to 24 months of age, which is based on milk, cereals and /or legumes (pulses), millets, nuts and protein concentrates or protein isolates and/or defatted edible oilseed extracts and so prepared as to permit dilution with water or milk or other suitable medium; | Existing |
| (j) “Processed cereal based complementary food” means food for infants after 6 months up to 24 months of age, which is based on cereals and legumes (pulses), millets, nuts and protein isolates or protein concentrates or de-fatted edible oil seed extracts and so prepared as to permit dilution with water or milk or other suitable medium; | Existing |

Stringent nutrient ranges

Existing

7.	Vitamin A (as retinol), µg per 100 g (not less than)	350
8.	Added Vitamin D (expressed as Cholecalciferol or Ergocalciferol), µg per 100g (not less than)	4.5
9.	Vitamin C, mg per 100 g (not less than)	35
10.	Thiamine, µg per 100 g (not less than)	185
11.	Riboflavin, µg per 100 g (not less than)	275
12.	Niacin, µg per 100 g (not less than)	1160
13.	Pyridoxine, µg per 100 g (not less than)	160
14.	Folic acid, µg per 100 g. (not less than)	20
15.	Pantothenic acid, mg per 100 g (not less than)	1.4
16.	Vitamin B ₁₂ , µg per 100 g (not less than)	0.7
17.	Choline, mg per 100 g (not less than)	32
18.	Vitamin K, µg per 100 g (not less than)	18
19.	Biotin, µg per 100 g (not less than)	7.0
20.	Vitamin E (as a-tocopherol compounds), IU per 100 g (not less than)	3.15
21.	Sodium, mg per 100 g (not less than)	90
22.	Potassium, mg per 100 g (not less than)	370
23.	Chloride, mg per 100 g (not less than)	250
24.	Calcium, mg per 100 g (not less than)	230
25.	Phosphorous, mg per 100 g (not less than)	115

New requirements

Sl. No.	Parameters	Requirements per 100 g	Requirements per 100 kcal
8.	Vitamin A (as retinol equivalent, RE), µg	350.00 - 823.00	75.00 - 175.00
9.	Vitamin D, µg	5.00 - 14.00	1.00 - 3.00
10.	Vitamin E (as alpha tocopherol equivalent), mg	2.50 - 6.00	0.50 - 1.30
11.	Vitamin K, µg	7.50 - 19.00	1.60 - 4.00
12.	Vitamin C, mg	25.00 - 75.00	5.30 - 16.00
13.	Thiamine, µg	200.00 - 517.00	42.50 - 110.00
14.	Riboflavin, µg	400.00 - 2000.00	85.10 - 425.50
15.	Niacin equivalent, mg	3.80 - 9.90	0.80 - 2.10
16.	Pyridoxine, µg	100.00 - 400.00	21.30 - 85.10
17.	Dietary Folate equivalent (DFE) ³ , µg	15.00 - 56.90	3.20 - 12.10
18.	Pantothenic acid, mg	2.00 - 10.00	0.42- 2.12
19.	Vitamin B12, µg	0.25 - 0.70	0.05 - 0.15
20.	Biotin, µg	7.50 - 50.00	1.60 - 10.60
21.	Choline, mg, Min	32.00	6.80
22.	Sodium, mg	90.00 - 300.00	19.15 - 63.80
23.	Potassium, mg	300.00 - 900.00	63.82 - 191.48

- (14) Wherever nutritional composition has been specified in 100 gm or 100 kcal basis under specific product categories in the composition tables, the FBO's shall comply with the nutrition composition in either per 100 gm or per 100 kcal basis.

Challenges

- Deviation from global standards- nutrient min and max not aligned with Codex



- Standard developed basis RDA inputs from NIN (theoretical)

- Practical difficulties not considered- like inherence of nutrients from raw material



Vitamin B12 and other nutrient advocacy

Sept 2020

- Concern were presented to the scientific panel on Vitamin B12
- Proposes to consider the inherent values coming from milk and milk solids used in the product, raise the maximum limit of vitamin B12 to 1.0 µg/100 Kcal in Infant Formula and in Follow-up Formula
- Post the meeting several submissions were made clarifying the technical aspect on analytical variability etc

Dec 2020

- Final Gazette was notified with no change in the vitamin B12 values and Typo graphical errors

Feb 3rd 2021

- Meeting with FSSAI on the Infant regulation
- Highlighted errors in units and values of various nutrient such as Calcium, Choline and Chromium, vitamin K etc.
- Reiterated the submission on Vitamin B12

Feb 12th 2021

- Submission were made on published data on vitamin b12 to show the biological variation of presence of vitamin B12 in milk.
- Operationalization of panel's recommendation is awaited, restricting industry to continue reformulation efforts.

March 2021

- Food Authority meeting agenda- Vit B12 max level fixed at 0.3mcg/100kcal
- Challenges w.r.t other nutrients still unresolved.

Additives alignment and additional ingredients

Existing

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 producing cultures Citric acid	Limited by Good Manufacturing Practice in all types of infant formulae
Antioxidants Mixed tocopherols concentrate and L-Ascorbyl palmitate	1 mg in all types of infant formulae
Mono and Diglycerides	0.4 g

New requirements

Allowance of FOS, GOS, precooked starch, lactose and glucose polymers

Food Additive	INS No.	Recommended maximum level per 100 ml of the product ready for consumption
		hydrolysed protein
Carob bean gum (Locust bean gum)	410	0.1 gm in all types of infant formula
Distarch phosphate	1412	0.5 gm singly or in combination in soy based infant formula only
Acetylated distarch phosphate	1414	2.5 gm singly or in combination in hydrolysed protein and / or amino acid based infant formula only
Phosphated distarch phosphate	1413	
Hydroxypropyl starch	1440	
Carrageenan	407	0.03 gm (in regular milk and soy based liquid infant formula only) 0.1 gm in hydrolysed protein and / or amino acid based liquid infant formula only
Emulsifiers		
Lecithin	322	0.5 gm in all types of infant formula*
Mono- and diglycerides	471	0.4 gm in all types of infant formula*
Citric and fatty acid esters of glycerol	472c	0.9 gm in all types of liquid infant formula 0.75 gm in all types of powdered infant formula
Acidity Regulators		
Sodium hydroxide	524	0.2 gm singly or in combination and within the limits for sodium, potassium and calcium in provision (g) of sub-regulation 7(1) in all types of infant formula
Sodium hydrogen carbonate	500ii	
Sodium carbonate	500i	
Potassium hydrogen carbonate	501ii	
Potassium carbonate	501i	
Potassium hydroxide	525	
Calcium hydroxide	526	
L(+)-lactic acid	270	
Citric acid	330	
Sodium dihydrogen citrate	331i	
Trisodium citrate	331iii	
Potassium citrate	332	
Sodium dihydrogen phosphate, disodium hydrogen phosphate and trisodium phosphate	339 i, ii and iii	45 mg as phosphorous singly or in combination and within limits for sodium, potassium and phosphorous in provision (g) of sub-regulation 7(1) in all types of infant formula
Potassium dihydrogen phosphate, dipotassium hydrogen phosphate and tripotassium phosphate	340 i, ii and iii	
Antioxidants		
Mixed tocopherol concentrate	307b	1 mg in all types of infant formula singly or in combination
Ascorbyl palmitate	304i	1 mg in all type of infant formula singly or in combination
Packaging gases		
Carbon dioxide	290	GMP
Nitrogen	941	

Labelling requirements

Labelling

Most existing labelling requirements retained.

Additional requirement:

(6) A warning against inherent contamination as under:

“Warning: Boiled and cooled water shall be used to prepare this product and any leftover product must be discarded to reduce the risk of infection”.

New sections- FSMP for infants including LBW, IEM

Chapter 4

Food for special medical purpose intended for infants

12. Food for special medical purpose intended for infants: This standard applies to food for special medical purpose intended for infants from birth to 24 months in liquid or powdered form intended for use, where necessary, as a substitute for human milk or formula in meeting the special nutritional requirements arising from the disorders, diseases or medical conditions for whose dietary management the product has been formulated.

Low Birth Weight formula = ESPHAGAN recommendations

Lactose free

Hypoallergenic

IEM (Inborn Error of Metabolism)- earlier covered under Diet4Life scheme

Summary

Document status	Timelines	Key advocacy agreed	Key advocacy pending
Pre draft document	Jan 2018	<ul style="list-style-type: none">Analytical variation $\pm 5\%$ removedNew standards for FSMP for infantsAdditives, sources of nutrients aligned with Codex	<ul style="list-style-type: none">Inherence issues- Vit B12Corrections in wrong units6 months too short timeline for reformulation of all products
Draft notification	May 2019		
Final notification	Dec 2020		
Implementation date	1 st July 2021		

Thank you

