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 FOOD SAFETY AND STANDARDS
 AUTHORITY OF INDIA
 Inspiring Trust, Assuring Safe & Nutritious Food

FAQS

Which products are covered under the scope of this direction?

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What is the date of implementation of this direction and who are bound by this direction?

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Will the IMS Act and the regulations thereunder be applicable to these foods?

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No. These foods are neither infant milk substitute nor infant food but are intended to meet special medical needs arising out of rare disorders/medical conditions. Further, these foods are required to be consumed under medical supervision. These foods are covered under special category of foods defined as Foods for Special Medical Purposes (FSMP) which are out of scope of the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992.

Will the import requirements change in anyway?

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What are the labelling requirements for these products?

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Will these foods for IEM disorders and hypoallergenic formula for allergic conditions require BIS certification mark?

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Will these foods for IEM disorders and hypoallergenic formula for allergic conditions fall under the scope of Second Schedule (for standard pack sizes) under Legal Metrology rules?

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Which are the ports where such products can be imported?

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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