CODEX STANDARD FOR INFANT FORMULA[1]

CODEX STAN 72-1981

1. SCOPE

This standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants. It also provides a standard for formulae intended for infants with special nutritional requirements, except for certain provisions which must be modified to meet those special requirements.

2. DESCRIPTION

2.1 Product Definitions

2.1.1 Infant formula, when in liquid form, may be used either directly or diluted with water before feeding, as appropriate. In powdered form it requires water for preparation.

2.1.2 The product shall be nutritionally adequate to promote normal growth and development when used in accordance with its directions for use.

2.1.3 The product is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 Other Definitions

2.2.1 The term ***infant*** means a person not more than 12 months of age.

2.2.2 The term ***calorie*** means a kilocalorie or "large calorie" (1 kilojoule is equivalent to 0.239 kilocalories).

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

3.1.1 Infant formula is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, which have been proved to be suitable for infant feeding.

3.1.2 Infant formula shall contain, per 100 available calories (or 100 kilojoules) of intake, the following minimum and maximum levels of vitamins, minerals in an available form, choline, protein, fat and linoleate:

	Amounts per 100 available calories		**Amounts per 100 available kilojoules**	
	Minimum	**Maximum**	**Minimum**	**Maximum**
Vitamins other than Vitamin E				
Vitamin A	250 I.U. or 75	500 I.U. or 150	60 I.U. or 18	120 I.U. or 37 µg

[1] The Codex Standard for Infant Formula was adopted by the Codex Alimentarius Commission at its 11th Session in 1976. In 1983, the 15th Session adopted amendments to the sections on Food Additives (carry-over) and Labelling. A further amendment to the Labelling Section was adopted in 1985 by the 16th Session. Amendments to the Vitamin D and B12 amounts were adopted by the 17th (1987) and 22nd (1997) Sessions respectively.

This standard has been submitted to all Member Nations and Associate Members of FAO and WHO for acceptance in accordance with the General Principles of the Codex Alimentarius.

	Amounts per 100 available calories		Amounts per 100 available kilojoules	
	µg expressed as retinol	µg expressed as retinol	µg expressed as retinol	expressed as retinol
Vitamin D	40 I.U.	100 I.U.	10 I.U.	25 I.U.
Ascorbic Acid (Vitamin C)	8 mg	N.S.[1]	1.9 mg	N.S.[1]
Thiamine (Vitamin B_1)	40 µg	N.S.[1]	10 µg	N.S.[1]
Riboflavin (Vitamin B_2)	60 µg	N.S.[1]	14 µg	N.S.[1]
Nicotinamide	250 µg	N.S.[1]	60 µg	N.S.[1]
Vitamin B_6[2]	35 µg	N.S.[1]	9 µg	N.S.[1]
Folic acid	4 µg	N.S.[1]	1 µg	N.S.[1]
Pantothenic acid	300 µg	N.S.[1]	70 µg	N.S.[1]
Vitamin B_{12}	0.1 µg	N.S.[1]	0.04 µg	N.S.[1]
Vitamin K_1	4 µg	N.S.[1]	1 µg	N.S.[1]
Biotin (Vitamin H)	1.5 µg	N.S.[1]	0.4 µg	N.S.[1]
Vitamin E (α -tocopherol compounds)	0.7 I.U./g linoleic acid[3], but in no case less than 0.7 I.U./100 available calories	N.S.[1]	0.7 I.U./g linoleic acid[3], but in no case less than 0.15 I.U./100 available kilojoules	N.S.[1]
Minerals				
Sodium (Na)	20 mg	60 mg	5 mg	15 mg
Potassium (K)	80 mg	200 mg	20 mg	50 mg
Chloride (Cl)	55 mg	150 mg	14 mg	35 mg
Calcium (Ca)[4]	50 mg	N.S.[1]	12 mg	N.S.[1]
Phosphorus (P)[4]	25 mg	N.S.[1]	6 mg	N.S.[1]
Magnesium (Mg)	6 mg	N.S.[1]	1.4 mg	N.S.[1]
Iron (Fe)	1 mg5	N.S.[1]	0.25 mg[2]	N.S.[1]
Iron (Fe)	0.15 mg	N.S.[1]	0.04 mg	N.S.[1]

1 N.S. = Not specified.

2 Formulae with a higher protein content than 1.8 g protein/100 Calories should contain a minimum of 15 µg Vitamin B_6 per gramme of protein.

3 Or per g polyunsaturated fatty acids, expressed as linoleic acid.

4 The Ca:P ratio shall be not less than 1.2 and not more than 2.0.

5 See Section 9.1.6.

	Amounts per 100 available calories		Amounts per 100 available kilojoules	
Iodine (I)	5 µg	N.S.[1]	1.2 µg	N.S.[1]
Copper (Cu)	60 µg	N.S.[1]	14 µg	N.S.[1]
Zinc (Zn)	0.5 mg	N.S.[1]	0.12 mg	N.S.[1]
Manganese (Mn)	5 µg	N.S.[1]	1.2 µg	N.S.[1]
Choline	7 mg	N.S.[1]	1.7 mg	N.S.[1]

Protein

(i) Shall not be less than 1.8 g per 100 available calories (or 0.43 g per 100 available kilojoules) of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in proportion to its biological value. The quality[1] of the protein shall not be less than 85% of that of casein. The total quantity of protein shall not be more than 4 g per 100 available calories (or 0.96 g per 100 available kilojoules). The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions.

(ii) Isolated amino acids may be added to Infant Formula only to improve its nutritional value for infants. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only natural L forms of amino acids shall be used.

Fat and Linoleate

The product shall contain linoleic acid (in the form of glycerides) at a level of not less than 300 mg per 100 available Calories (or 70 mg per 100 available kilojoules) and fat at a level not less than 3.3 g and not more than 6 g per 100 available Calories (or not less than 0.8 g and not more than 1.5 g per 100 available kilojoules).

3.2 Optional Ingredients

3.2.1 In addition to the vitamins and minerals listed under 3.1.2, other nutrients may be added when required in order to provide nutrients ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrients of the infant.

3.2.2 The usefulness of these nutrients shall be scientifically shown.

3.2.3 When any of these nutrients is added, the formula shall contain significant amounts of these nutrients, based on levels in human milk.

3.3 Vitamin Compounds and Mineral Salts

3.3.1 Vitamins and minerals added in accordance with Section 3.1.2 (a,b,c,d) and 3.2.1 should be selected from the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).

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[1] Protein quality shall be determined provisionally using the PER method as laid down in the section dealing with methods of analysis, it being understood that the suitability of the product for infant feeding in conformity with Section 2.1.2 of this Standard will have been established on the basis of adequate and appropriate tests in the light of current knowledge.

3.3.2 The amounts of sodium and potassium derived from the added vitamins and/or minerals shall be within the limits for sodium and potassium in Section 3.1.2(c).

3.4 Consistency and Particle Size

When prepared according to the label directions for use, the product shall be free of lumps and of large coarse particles and suitable for being fed through a soft rubber or plastic nipple.

3.5 Purity Requirements

All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.6 Specific Prohibition

The product and its components shall not have been treated by ionizing radiation.

4. FOOD ADDITIVES

The following additives are permitted in the preparation of Infant Formula, as described in Section 1 of this Standard, and with the restrictions stated below:

Group and INS number	Additive	Maximum level in 100 ml of the ready-to-drink product
4.1 Thickening Agents		
412	Guar gum	0.1 g in all types of infant formula
410	Carob bean gum (Locust bean gum)[1]	0.1 g in all types of infant formula
1412 1414 1413 1440	Distarch phosphate Acetylated distarch phosphate Phosphated distarch phosphate Hydroxypropyl starch	0.5 g singly or in combination in soy-based infant formulae only 2.5 g singly or in combination in hydrolyzed protein acid-based infant formulae only and/or amino acid
407	Carrageenan	0.03 g in regular, milk- and soy- based liquid infant formulae only 0.1 g in hydrolyzed protein and/or amino acid-based liquid infant formulae only
4.2 Emulsifiers		
322	Lecithin	0.5 g in all types of infant formulae
322	Mono- and diglycerides	0.4 g in all types of infant formulae
4.3 pH-Adjusting Agents		
524 500(ii) 500(i) 525	Sodium hydroxide Sodium hydrogen carbonate Sodium carbonate Potassium hydroxide	Limited by good manufacturing practice and within the limits for sodium and potassium in Section 3.1.2 (c) in all types of infant formulae

1 Temporarily endorsed.

501(ii)	Potassium hydrogen carbonate	
501(i)	Potassium carbonate	
526	Calcium hydroxide	
331	Sodium citrate	
332	Potassium citrate	
270	L(+) Lactic acid	Limited by good manufacturing practice in all types of infant formulae
	L(+) Lactic acid producing cultures	
330	Citric acid	
330		
4.4 Antioxidants		
306	Mixed tocopherols concentrate	1 mg in all types of infant formulae
304	L-Ascorbyl palmitate	

4.5 Carry-over of Food Additives

No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception:

(a) of the food additives listed under Sections 4.1 to 4.4 of this standard within the limits of the maximum levels stipulated in this standard; and

(b) of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.

5. CONTAMINANTS

5.1 Pesticide Residues

The product 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 ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

5.2 Other Contaminants

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

6. HYGIENE

6.1 To the extent possible in good manufacturing practice, the product shall be free from objectionable matter.

6.2 When tested by appropriate methods of sampling and examination, the product:

(a) shall be free from pathogenic microorganisms;

(b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and

(c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

6.3 The product shall be prepared, packed and held under sanitary conditions and should comply with the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).

7. PACKAGING

7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media.

7.2 The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

8. FILL OF CONTAINER

In the case of products in ready-to-eat form, the fill of container shall be:

(i) not less than 80% v/v for products weighing less than 150 g (5 oz.);

(ii) not less than 85% v/v for products in the weight range 150-250 g (5-8 oz.); and

(iii) not less than 90% v/v for products weighing more than 250 g (8 oz.)

of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20^{o} C which the sealed container will hold completely filled.

9. LABELLING

In addition to the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991) Codex Alimentarius Volume 1), the following specific provisions apply:

9.1 The Name of the Food

9.1.1 The name of the product shall be either "Infant Formula" or any appropriate designation indicating the true nature of the product, in accordance with national usage.

9.1.2 The sources of protein in the product shall be clearly shown on the label.

9.1.3 If 90% or more of the protein is derived from whole or skim milk, as such or with minor modification, the product may be labelled "Infant Formula Based on Milk".

9.1.4 A product which contains neither milk or any milk derivative may be labelled "contains no milk or milk products" or an equivalent phrase.

9.1.5 A product intended for infants with special nutritional requirements shall be labelled to show clearly the special requirement for which the formula is to be used and the dietary property or properties on which this is based.

9.1.6 Products containing not less than 1 mg Iron (Fe)/100 available calories shall be labelled "Infant Formula with Iron".

9.2 List of Ingredients

9.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.

9.3 Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information in the following order:

(a) the amount of energy, expressed in Calories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption;

(b) the total quantity of each vitamin, mineral, choline and any optional ingredient as listed in paragraphs 3.1.2 and 3.2 of this Standard per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 calories (or per 100 kilojoules) is permitted.

9.4 Date Marking and Storage Instructions

9.4.1 The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer.

In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon.

Where practicable, storage instructions shall be in close proximity to the date marking.

9.5 Information for Utilization

9.5.1 Directions as to the preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label or on the accompanying leaflet.

9.5.2 Information that infants over six months of age should receive supplemental foods in addition to the formula shall appear on the label.

9.6 Optional Labelling

An indication that Infant Formula is intended to replace or supplement breast-feeding, where breast-feeding is not possible or is insufficient, may be given on the label. In this case, the provisions of Article 9 of the International Code of Marketing of Breast-Milk Substitutes of the World Health Organization should be duly taken into account.

10. METHODS OF ANALYSIS AND SAMPLING

See Codex Alimentarius Volume 13.