

**PAKISTAN STANDARDS SPECIFICATION
FOR
FOOD FOR INFANT AND CHILDREN**

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FOR
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CONTENTS

S. NO.	TITLE	PAGE NO
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	

**PAKISTAN STANDARD SPECIFICATION
FOR
FOOD FOR INFANTS AND CHILDREN**

0. FOREWORD

- 0.1 This Pakistan Standard was adopted by the Pakistan Standards Institution on 15th March, 1985 on the endorsement by the Agriculture and Food Products Divisional Council after the draft finalized by the Milk and Dairy Products Sectional Committee.
- 0.2 Food for Infants and Children is in liquid or powdered forms intended for use, where necessary as a substitute for human milk in meeting the normal nutritional requirements of infants.
- 0.3 The views of producers, consumers, testing authorities, food technologists and nutritionist were taken into consideration while formulating this standard.
- 0.4 The quantities and dimensions appearing in this standard have been given in International system.
- 0.5 For the purpose of deciding whether a particular requirement of this standard is complied with the final value observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with PS:103 Methods for Rounding Off Numerical Values, the number of significant placed retained in the rounded off value shall be the same as that of the specified value in this standard.
- 06. This standard is intended chiefly to cover the technical provisions relating to food for Infant and Children, and it does not include all the necessary provision of a contract.

1. SCOPE

- 1.1 This standard applies to Food for Infants & Children in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants and young children. It also provides a standard for formulae intended for infant with special medical purposes, except for certain provisions which must be modified to meet that special requirement

2. DESCRIPTION

- 2.1 Food for Infants & Children 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
- 2.2 The product shall be nutritionally adequate to promote normal growth and development when used in accordance with its directions for use.
- 2.3 The product is so processed and packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

SECTION A: REVISED STANDARD FOR INFANT FORMULA

PREAMBLE

This standard is divided into two sections. Section A refers to Infant Formula, and Section B deals with Formulas for Special Medical Purposes Intended for Infants.

1. SCOPE

1.1 This section of the 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.

1.2 This section of the Standard contains compositional, quality and safety requirements for Infant Formula.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for marketing as infant formula. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.

1.4 The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001).

2. DESCRIPTION

2.1 Product Definition

2.1.1 Infant formula means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding.

2.1.2 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

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

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 or a mixture thereof and/or other ingredients which have been proven to be suitable for infant feeding. The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants. All ingredients and food additives shall be gluten-free.

3.1.2 Infant formula prepared ready for consumption in accordance with instructions of the manufacturer shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (295 kJ) of energy.

3.1.3 Infant formula prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL)¹, as appropriate. The general principles for establishing these levels are identified in Annex II of this standard.

a) Protein^{2), 3), 4)}

Unit	Minimum	Maximum	GUL
------	---------	---------	-----

g/100 kcal	1.8 ^{5), 6)}	3.0	-
g/100 kJ	0.45 ^{5), 6)}	0.7	-

2)

For the purpose of this standard, the calculation of the protein content of the final product prepared ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.

3)

For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I); nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine may be added together. The concentrations of methionine and cysteine may be added together if the ratio is less than 2:1; in the case that the ratio is between 2:1 and 3:1 the suitability of the formula has to be demonstrated by clinical testing.

4)

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

5)

The minimum value applies to cows' milk protein. For infant formula based on non-cows' milk protein other minimum values may need to be applied. For infant formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.5 g/100 kJ) applies.

6)

Infant formula based on non-hydrolysed milk protein containing less than 2 g protein/ 100 kcal and infant formula based on hydrolysed protein containing less than 2.25 g protein/ 100 kcal should be clinically evaluated.

b) Lipids

Total fat^{7), 8)}

Unit	Minimum	Maximum	GUL
g/100 kcal	4.4	6.0	-
g/100 kJ	1.05	1.4	-

7)

Commercially hydrogenated oils and fats shall not be used in infant formula.

8)

Lauric and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3 % of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in infant formulae. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

1

Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in infant formulas should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

Linoleic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	300	-	1400
mg/100 kJ	70	-	330

α -Linolenic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	50	N.S.*	-
mg/100 kJ	12	N.S.	-

*N.S. = not specified

Ratio linoleic/ α -linolenic acid

Min	Max
5:1	15:1

c) Carbohydrates

Total carbohydrates⁹⁾

Unit	Minimum	Maximum	GUL
g/100 kcal	9.0	14.0	-
g/100 kJ	2.2	3.3	-

⁹⁾

Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added to Infant Formula up to 30% of total carbohydrates and up to 2 g/100 ml.

Sucrose, unless needed, and the addition of fructose as an ingredient should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance.

d) Vitamins

Vitamin A

Unit	Minimum	Maximum	GUL
$\mu\text{g RE}^{10)}/100 \text{ kcal}$	60	180	-
$\mu\text{g RE}^{10)}/100 \text{ kJ}$	14	43	-

¹⁰⁾

expressed as retinol equivalents (RE).

1 $\mu\text{g RE}$ = 3.33 IU Vitamin A = 1 μg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Vitamin D₃

Unit	Minimum	Maximum	GUL
$\mu\text{g}^{11)}/100 \text{ kcal}$	1	2.5	-
$\mu\text{g}^{11)}/100 \text{ kJ}$	0.25	0.6	-

¹¹⁾

Calciferol. 1 μg calciferol = 40 IU vitamin D

Vitamin E

Unit	Minimum	Maximum	GUL
mg α -TE ¹²⁾ /100 kcal	0.5 ¹³⁾	-	5
mg α -TE ¹²⁾ /100 kJ	0.12 ¹³⁾	-	1.2

¹²⁾ 1 mg α -TE (alpha-tocopherol equivalent) = 1 mg d- α -tocopherol

¹³⁾ Vitamin E content shall be at least 0.5 mg α -TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: 0.5 mg α -TE/g linoleic acid (18:2 n-6); 0.75 α -TE/g α -linolenic acid (18:3 n-3); 1.0 mg α -TE/g arachidonic acid (20:4 n-6); 1.25 mg α -TE/g eicosapentaenoic acid (20:5 n-3); 1.5 mg α -TE/g docosahexaenoic acid (22:6 n-3).

Vitamin K

Unit	Minimum	Maximum	GUL
μ g/100 kcal	4	-	27
μ g/100 kJ	1	-	6.5

Thiamin

Unit	Minimum	Maximum	GUL
μ g/100 kcal	60	-	300
μ g/100 kJ	14	-	72

Riboflavin

Unit	Minimum	Maximum	GUL
μ g/100 kcal	80	-	500
μ g/100 kJ	19	-	119

Niacin¹⁴⁾

Unit	Minimum	Maximum	GUL
μ g/100 kcal	300	-	1500
μ g/100 kJ	70	-	360

¹⁴⁾ Niacin refers to preformed niacin.

Vitamin B₆

Unit	Minimum	Maximum	GUL
μ g/100 kcal	35	-	175
μ g/100 kJ	8.5	-	45

Vitamin B₁₂

Unit	Minimum	Maximum	GUL
μ g/100 kcal	0.1	-	1.5
μ g/100 kJ	0.025	-	0.36

Pantothenic acid

Unit	Minimum	Maximum	GUL
µg/100 kcal	400	-	2000
µg/100 kJ	96	-	478

Folic acid

Unit	Minimum	Maximum	GUL
µg/100 kcal	10	-	50
µg/100 kJ	2.5	-	12

Vitamin C¹⁵⁾

Unit	Minimum	Maximum	GUL
mg/100 kcal	10	-	70 ¹⁶⁾
mg/100 kJ	2.5	-	17 ¹⁶⁾

¹⁵⁾ expressed as ascorbic acid

¹⁶⁾ This GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products lower upper levels should be aimed for.

Biotin

Unit	Minimum	Maximum	GUL
µg/100 kcal	1.5	-	10
µg/100 kJ	0.4	-	2.4

e) Minerals and Trace Elements

Iron

Unit	Minimum	Maximum	GUL ¹⁷⁾
mg/100 kcal	0.45	-	-
mg/100 kJ	0.1	-	-

¹⁷⁾ Levels may need to be determined by national authorities.

Calcium

Unit	Minimum	Maximum	GUL
mg/100 kcal	50	-	140
mg/100 kJ	12	-	35

Phosphorus

Unit	Minimum	Maximum	GUL
mg/100 kcal	25	-	100 ¹⁸⁾
mg/100 kJ	6	-	24 ¹⁸⁾

¹⁸⁾ This GUL should accommodate higher needs with soy formula.

Ratio calcium/ phosphorus

Min	Max
1:1	2:1

Magnesium

Unit	Minimum	Maximum	GUL
mg/100 kcal	5	-	15
mg/100 kJ	1.2	-	3.6

Sodium

Unit	Minimum	Maximum	GUL
mg/100 kcal	20	60	-
mg/100 kJ	5	14	-

Chloride

Unit	Minimum	Maximum	GUL
mg/100 kcal	50	160	-
mg/100 kJ	12	38	-

Potassium

Unit	Minimum	Maximum	GUL
mg/100 kcal	60	180	-
mg/100 kJ	14	43	-

Manganese

Unit	Minimum	Maximum	GUL
µg/100 kcal	1	-	100
µg/100 kJ	0.25	-	24

Iodine

Unit	Minimum	Maximum	GUL
µg/100 kcal	10	-	60
µg/100 kJ	2.5	-	14

Selenium

Unit	Minimum	Maximum	GUL
µg/100 kcal	1	-	9
µg/100 kJ	0.24	-	2.2

Copper¹⁹⁾

Unit	Minimum	Maximum	GUL
µg/100 kcal	35	-	120
µg/100 kJ	8.5	-	29

¹⁹⁾ Adjustment may be needed in these levels for infant formula made in regions with a high content of copper in the water supply.

Zinc

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.5	-	1.5
mg/100 kJ	0.12	-	0.36

f) Other Substances

Choline

Unit	Minimum	Maximum	GUL
mg/100 kcal	7	-	50
mg/100 kJ	1.7	-	12

Myo-Inositol

Unit	Minimum	Maximum	GUL
mg/100 kcal	4	-	40
mg/100 kJ	1	-	9.5

L-Carnitine

Unit	Minimum	Maximum	GUL
mg/100 kcal	1.2	N.S.	-
mg/100 kJ	0.3	N.S.	-

3.2 Optional ingredients

3.2.1 In addition to the compositional requirements listed under 3.1.3, other ingredients may be added in order to provide substances ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to outcomes of populations of breastfed babies.

3.2.2 The suitability for the particular nutritional uses of infants and the safety of these substances shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect, taking into account levels in human milk.

3.2.3 The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100 kJ) in the Infant Formula ready for consumption shall not exceed:

Taurine

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	12	-
mg/100 kJ	-	3	-

Total nucleotides

Levels may need to be determined by national authorities.

Docosahexaenoic Acid²⁰⁾

Unit	Minimum	Maximum	GUL
% of fatty acids	-	-	0.5

20)

If docosahexaenoic acid (22:6 n-3) is added to infant formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. National authorities may deviate from the above conditions, as appropriate for the nutritional needs.

3.2.4 Only L(+)-lactic acid producing cultures may be used.

3.3 Fluoride

Fluoride should not be added to infant formula. In any case its level should not exceed 100 µg /100 kcal (24µg/100 kJ) in infant formula prepared ready for consumption as recommended by the manufacturer.

3.4 Vitamin Compounds and Mineral Salts

Vitamins and minerals added in accordance with Section 3.1.3 (d and e) and other nutrients added in accordance with 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) or PSQCA list -----

3.5 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 adequate feeding of young infants.

3.6 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.

3.7 Specific Prohibitions

The product and its component shall not have been treated by ionizing irradiation.

4. FOOD ADDITIVES

Only the food additives listed in this Section or PSQCA list-----or in the Codex Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

- a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and
- b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CAC/STAN 192-1995 or PSQCA list-----).

The following food additives are acceptable for use in the preparation of infant formula, as described in Section 2.1 of this Standard (in 100 ml of product, ready for consumption prepared following manufacturer's instructions, unless otherwise indicated):

INS	Additive	Maximum level in 100 ml of the product ready for consumption
4.1 Thickeners		
412	Guar gum	0.1 g in liquid formulas containing hydrolysed protein
410	Carob bean gum (Locust bean gum)	0.1 g in all types of infant formula

1412	Distarch phosphate	0.5 g singly or in combination in soy-based infant formula only
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1440	Hydroxypropyl starch	2.5 g singly or in combination in hydrolyzed protein- and/or amino acid based infant formula only
407	Carrageenan ₂	0.03 g in regular milk- and soy-based liquid infant formula only 0.1 g in hydrolysed protein- and/or amino acid based liquid infant formula only
4.2 Emulsifiers		
322	Lecithins	0.5 g in all types of infant formula ²²⁾
471	Mono- and diglycerides	0.4 g in all types of infant formula ²²⁾
4.3 Acidity Regulators		
524	Sodium hydroxide	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in section 3.1.3 (e) in all types of infant formula
500ii	Sodium hydrogen carbonate	
500i	Sodium carbonate	
525	Potassium hydroxide	
501ii	Potassium hydrogen carbonate	
501i	Potassium carbonate	
526	Calcium hydroxide	
270	L(+) lactic acid	

² Not endorsed by the 39th Session of the CCFA. JECFA evaluation is pending. national authorities may restrict its use until JECFA evaluation has been completed. ²²⁾ If more than one of the substances INS 322, 471 are added the maximum level for each of those substances is lowered with the relative part as present of the other substances

INS Additive Maximum level in 100 ml of the product ready for consumption

330	Citric acid	Limited by GMP in all types of infant formula
331i	Sodium dihydrogen citrate	Limited by GMP in all types of infant formula
331iii	Trisodium citrate	Limited by GMP in all types of infant formula
332	Potassium citrate	Limited by GMP in all types of infant formula
4.4 Antioxidants		
307b	Mixed tocopherol concentrate	1 mg in all types of infant formula singly or in combination
304i	Ascorbyl palmitate	1 mg in all types of infant formula singly or in combination
4.9 Packaging Gases		
290	Carbon dioxide	GMP
941	Nitrogen	

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 not contain contaminants or undesirable substances (e.g. biologically active substances) in amounts which may represent a hazard to the health of the infant. The product covered by the provisions of the Standard shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission.

Maximum level

Lead 0.02 mg/kg (in the ready-to-use product)

6. HYGIENE

6.1 It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969), and other relevant Codex texts such as the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).

6.2 The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

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° C which the sealed container will hold completely filled.

9. LABELLING

The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims apply to infant formula and formula for special medical purposes for infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation. In addition to these requirements the following specific provisions apply:

9.1 The Name of the Food

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.1.2 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.

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

9.1.4 If cows' milk is the only source of protein, the product may be labelled "Infant Formula Based on Cows' Milk".

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

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 minerals, these ingredients may be arranged as separate groups for vitamins and minerals. 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 which should be in the following order:

- a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes or per 100 milliliters of the food as sold as well as per 100 milliliters of the food ready for use, when prepared according to the instructions on the label.
- b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.3 and any other ingredient as listed in paragraph 3.2 of this Standard per 100 grammes or per 100 milliliters of the food as sold as well as per 100 milliliters of the food ready for use, when prepared according to the instructions on the label.
- c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (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 Use

9.5.1 Products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula remaining after feeding should be discarded, shall appear on the label and in any accompanying leaflet.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.

9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label and in any accompanying leaflet.

9.6 Additional Labelling Requirements

9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

- a) the words "important notice" or their equivalent;
- b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;

c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use.

9.6.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula.

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

9.6.4 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

9.6.5 The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.

10. METHODS OF ANALYSIS AND SAMPLING₃

To be finalized.

Essential and semi-essential amino acids in breast milk*

For the purpose of this Standard the essential and semi-essential amino acids in human milk from published studies which report measurements of the total nitrogen content and/or the calculation method of the protein content, expressed as mg per g of nitrogen and as mg per 100 kcal are listed.

The average level of an amino acid (mg per g of nitrogen) from each study was used to calculate the corresponding amino acid content per 100 kcal of an infant formula with the minimum protein content of 1.8 g/ 100 kcal accepted in this Standard (mg amino acid/g nitrogen in breast-milk divided by the nitrogen conversion factor of 6.25 and multiplied by 1.8).

The mean of the sums of the average amino acid levels from all studies was converted in the same manner to the average amounts of an amino acid per g of protein (total nitrogen x 6.25) and per 100 kcal of energy (columns 19 and 20 of the table).

National authorities may use all of the listed values.

- *Adapted from Koletzko B, Baker S, Cleghorn G, et al, Global standard for the composition of infant formula: Recommendations of ESPGHAN coordinated international expert group. J Pediatr Gastroenterol Nutr. 2005;41:584-599*

	Lönnerdal & Forsum (1985)		Darragh & Moughan (1998)		Bindels & Harzer (1985)		Janas et al. (1987)		Villalpando et al. (1998)				Räihä et al. (2002) mod Nayman et al. (1979)		Yonekubo et al. (1991)		Mean of all amino acids contents		
	Pooled banked milk at 4-16 weeks		Pooled over 20 days at 10-14 weeks (n=20)		24 hours, pooled at 5 weeks (n=10)		24 hours, pooled at 8 weeks (n=10)		24 hours, pooled at 4-6 months				Pooled banked milk at >1 month		Milk at 21 days -2 months				
									Mexico (n=40)		Houston (n=40)								
mg amino acid per	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g nitrogen	g nitrogen	100 kcal
Cysteine	111	32	173	50	108	31	101	29	167	48	134	39	133	38	118	34	131	21	38
Histidine	111	32	156	45	255	73	112	32	112	32	108	31	122	35	150	43	141	23	41

	Lönnerdal & Forsum (1985)		Darragh & Moughan (1998)		Bindels & Harzer (1985)		Janas et al. (1987)		Villalpando et al. (1998)				Räihä et al. (2002) mod Nayman et al. (1979)		Yonekubo et al. (1991)		Mean of all amino acids contents		
	Pooled banked milk at 4-16 weeks		Pooled over 20 days at 10-14 weeks (n=20)		24 hours, pooled at 5 weeks (n=10)		24 hours, pooled at 8 weeks (n=10)		24 hours, pooled at 4-6 months				Pooled banked milk at >1 month		Milk at 21 days -2 months				
									Mexico (n=40)		Houston (n=40)								
mg amino acid per	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g nitro-gen	g nitro-gen	100 kcal
Isoleucine	242	70	333	96	376	108	306	88	292	84	331	95	300	86	37	108	319	51	92
Leucine	457	132	598	172	713	205	611	176	528	152	541	156	572	165	66	192	586	94	169
Lysine	314	90	406	117	522	150	365	105	366	105	408	118	361	104	42	121	395	63	114
Methionine	78	22	90	26	89	26	73	21	99	29	76	22	83	24	92	26	85	14	24
Phenylalanine	153	44	243	70	344	99	183	53	440	127	439	126	217	62	24	69	282	45	81
Threonine	217	62	316	91	344	99	251	72	248	71	242	70	256	74	26	77	268	43	77
Tryptophan	NA		NA		172	50	79	23	112	32	89	26	111	32	12	35	114	18	33
Tyrosine	201	58	241	69	369	106	191	55	292	84	299	86	233	67	24	72	259	42	75

	Lönnerdal & Forsum (1985)		Darragh & Moughan (1998)		Bindels & Harzer (1985)		Janas et al. (1987)		Villalpando et al. (1998)				Räihä et al. (2002) mod Nayman et al. (1979)		Yonekubo et al. (1991)		Mean of all amino acids contents		
	Pooled banked milk at 4-16 weeks		Pooled over 20 days at 10-14 weeks (n=20)		24 hours, pooled at 5 weeks (n=10)		24 hours, pooled at 8 weeks (n=10)		24 hours, pooled at 4-6 months				Pooled banked milk at >1 month		Milk at 21 days –2 months				
	mg amino acid per	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g N	100 kcal	g nitro-gen	g nitro-gen
Valine	253	73	327	94	376	108	267	77	286	82	331	95	317	91	364	105	315	50	90

References

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GENERAL PRINCIPLES FOR ESTABLISHING MINIMUM AND MAXIMUM VALUES FOR THE ESSENTIAL COMPOSITION OF INFANT FORMULA

1. The goal of establishing minimum and maximum values is to provide safe and nutritionally adequate infant formula products that meet the normal nutritional requirements of infants.
2. A nutritionally adequate infant formula will promote growth and development consistent with science based standards and meet the nutritional requirements of infants when fed as a sole source of nutrition during the first months of life up to the introduction of appropriate complementary feeding.
3. The values to be established are based on an independent evaluation, in particular of the scientific evidence of the amounts needed to meet the nutritional requirements of infants, considering relevant human infant studies and the composition of breast-milk.
4. In addition to the principles set out in No. 3, when setting minimum and maximum values, consideration will also be given to the safety of such values.

For nutrients with a documented risk of adverse health effects the upper levels to be taken into account will be determined using a science-based risk assessment approach. Where scientific data are not sufficient for a science-based risk assessment, consideration should be given to an established history of apparently safe use of the nutrient in infants, as appropriate. Values derived on the basis of meeting the nutritional requirements of infants and an established history of apparently safe use should be considered as interim guidance upper levels. The approach to setting maximum and upper guidance values shall be made transparent and comprehensible.

5. When establishing minimum and maximum amounts, the following should also be taken into account:

- a) bioavailability, processing losses and shelf-life stability from the ingredients and formula matrix,
- b) total levels of a nutrient in infant formula, taking into account both naturally occurring nutrients in the ingredients and added nutrients,
- c) the inherent variability of nutrients in ingredients and in water that may be added to the infant formula during manufacture.

6. Overages for individual nutrients, as appropriate, to ensure that the required minimum levels are met throughout the shelf-life of the formula, will be included in the maximum value.

7. In establishing minimum or maximum amounts of nutrients per 100 kcal (or per 100 kJ) of infant formula based on consideration of reference values for the nutrients expressed as units per daily intake or per kilogram of body weight, the following assumptions will be considered:

- a) The mean intake of prepared formula for infants from birth to six months of age is 750 ml per day, and
 - b) a representative body weight for an infant over this period is 5 kg,
- and
- c) a representative caloric intake of an infant over this period is 500 kcal per day (or 100 kcal/kg/day).

Modifications of the approach may be needed when there is justification for deviating from one or more of these assumptions with regard to the specific formula product or specific infant population group.

SECTION B: FORMULA FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

1. SCOPE

1.1 This section of the Standard applies to Formula for Special Medical Purposes Intended for Infants in liquid or powdered form intended for use, where necessary, as a substitute for human milk or infant formula in meeting the special nutritional requirements arising from the disorder, disease or medical condition for whose dietary management the product has been formulated.

1.2 This section of the Standard contains compositional, quality, labelling and safety requirements for Formula for Special Medical Purposes Intended for Infants.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this standard would be accepted for marketing as formula for special medical purposes intended for infants.

1.4 The application of this section of the Standard should take into account, as appropriate for the products to which the section applies and the special needs of the infants for whom they are intended, the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001).

2. DESCRIPTION

2.1 Product definition

2.1.1 Formula for Special Medical Purposes Intended for Infants means a substitute for human milk or infant formula that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.

2.1.2

See Section A 2.1.2

2.2 Other Definitions

See Section A 2.2

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

3.1.1. Formula for Special Medical Purposes intended for Infants is a product based on ingredients based of animal, plant and/or synthetic origin suitable for human consumption. All ingredients and food additives shall be gluten-free.

3.1.2 The composition of Formula for Special Medical Purposes Intended for Infants shall be based on sound medical and nutritional principles. The nutritional safety and adequacy of the formula shall be scientifically demonstrated to support growth and development in the infants for whom it is intended,

as appropriate for the specific products and indications. Their use shall be demonstrated by scientific evidence to be beneficial in the dietary management of the infants for whom it is intended.

3.1.3 The energy content and nutrient composition of Formula for Special Medical Purposes intended for infants shall be based on the requirements for infant formula as given in sections A 3.1.2 and A 3.1.3, except for the compositional provisions which must be modified to meet the special nutritional requirements arising from the disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specifically formulated, labelled and presented.

3.1.4 In addition to the requirements in 3.1.3 the following requirements shall also be taken into account, where appropriate:

Chromium

Unit	Minimum	Maximum	GUL
µg/100 kcal	1.5	-	10
µg/100 kJ	0.4	-	2.4

Molybdenum

Unit	Minimum	Maximum	GUL
µg/100 kcal	1.5	-	10
µg/100 kJ	0.4	-	2.4

3.2 Optional ingredients

3.2.1 In addition to the compositional requirements listed under 3.1.3, other ingredients may be added in order to provide substances ordinarily found in human milk or required to ensure that the formulation is suitable as the sole source of nutrition for the infant and for the dietary management of his/her disease, disorder or medical condition.

3.2.2 The suitability for the intended special medical purpose, the suitability for the particular nutritional use of infants and the safety of these substances shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect.

3.2.3 Only L(+)lactic acid producing cultures may be used in Formulas for Special Medical Purposes for infants if shown to be safe and appropriate for use in these vulnerable populations.

3.3 Vitamin Compounds and Mineral Salts

See Section A 3.4

3.4 Consistency and Particle Size

See Section A 3.5

3.5 Purity Requirements

See Section A 3.6

3.6 Specific Prohibitions

See Section A 3.7

4. FOOD ADDITIVES

See Section A 4.

5. CONTAMINANTS

See Section A 5.

6. HYGIENE

See Section A 6.

7. PACKAGING

See Section A 7.

8. FILL OF CONTAINER

See Section A 8.

9. LABELLING

See introductory paragraph of Section A 9.

9.1 The Name of the Food

9.1.1 See Section A 9.1.1

9.1.2 The name of the product shall be "Formula for Special Medical Purposes Intended for Infants" or any appropriate designation indicating the true nature of the product, in accordance with national usage.

9.1.3 If cows' milk is the only source of protein, the product may be labelled "Formula for Special Medical Purposes Intended for Infants Based on Cows' Milk".

9.2 List of Ingredients

See Section A 9.2

9.3 Declaration of Nutritive Value

Formula for Special Medical Purposes Intended for Infants shall be labelled with complete nutrition labelling according to Section 4.2 of Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).

9.4 Date Marking and Storage Instructions

See Section A 9.4

9.5 Information for Use

See Section A 9.5

9.6 Additional Labelling Requirements

9.6.1 Formula for Special Medical Purposes Intended for Infants shall be labelled with the additional information as specified in Sections 4.4.1, 4.4.3, 4.4.4, 4.5.1 and 4.5.5 of CODEX STAN 180-1991.

9.6.2 A prominent statement indicating that the product is intended as the sole source of nutrition shall appear on the label.

9.6.3 In addition, the information specified in Sections 4.5.2, 4.5.3 and 4.5.6 of CODEX STAN 180-1991 shall be included on the label or be provided separately from the package.

9.6.4 Labels and information provided separately from the package should not discourage breastfeeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical condition(s) for which the product is intended.

9.6.5

See Section A 9.6.5

10. Methods of Analysis

See Section A 10.

INTRODUCTION

2. DESCRIPTION

- 2.1 Food for Infants & Children 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
- 2.2 The product shall be nutritionally adequate to promote normal growth and development when used in accordance with its directions for use.
- 2.4 The product is so processed and packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

Pakistan Standard Specification for Follow up Formula

1. SCOPE

This standard applies to the composition and labelling of follow-up formula.

2. DESCRIPTION

2.1 Definitions

2.1.1 **Follow-up formula** means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.

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

2.1.3 The term **young children** means persons from the age of more than 12 months up to the age of three years (36 months).

2.1.4 The term **calorie** means a kilocalorie (kcal). 1 kilojoule (kJ) is equivalent to 0.239 calories (kcal).

2.2 **Follow-up formula** is a food prepared from the milk of cows or other animals and/or other

Constituents of animal and/or plant origin, which have been proved to be suitable for infants from the 6th month on and for young children.

2.3 Follow-up formula is a food processed by physical means only so as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.

2.4 Follow-up formula, when in liquid form, is suitable for use either directly or diluted with water before feeding, as appropriate. In powdered form it requires water for preparation. The product shall be nutritionally adequate to contribute to normal growth and development when used in accordance with its directions for use.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Energy Content

When prepared in accordance with the instructions for use, 100 ml of the ready-for-consumption product shall provide not less than 60 kcal (or 250 kJ) and not more than 85 kcal (or 355 kJ).

3.2 Nutrient Content

Follow-up formula shall contain the following nutrients at minimum and maximum levels indicated below:

3.2.1 Protein

3.2.1.1 Not less than 3.0 g per 100 available calories (or 0.7 g per 100 available kilojoules) of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in inverse proportion to its nutritional quality. The quality of the protein shall not be less than 85% of that of casein. The total quantity of protein shall not be more than 5.5 g per 100 available calories (or 1.3 g per 100 available kilojoules).

3.2.1.2 Essential amino acids may be added to follow-up formula only to improve its nutritional value.

Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose.

Only L forms of amino acids shall be used.

3.2.2 Fat

3.2.2.1 Not less than 3 g and not more than 6 g per 100 calories (0.7 and 1.4 g per 100 available kilojoules).

3.2.2.2 The level of linoleic acid (in the form of a glyceride) shall not be less than 300 mg per 100 calories (or 71.7 mg per 100 available kilojoules).

3.2.3 Carbohydrates

The product shall contain nutritionally available carbohydrates suitable for the feeding of the older infant and the young child in such quantities as to adjust the product to the energy density in accordance with the requirements set out in Section 3.1.

¹ Protein quality shall be determined provisionally using the PER method as laid down in the section dealing with methods of analysis.

Vitamins and Minerals

3.2.4 Vitamins other than Vitamin E	Amounts per 100 available calories		Amounts per 100 available kilojoules	
	Minimum	Maximum	Minimum	Maximum
Vitamin A	250 I.U. or 75 µg	750 I.U. or 225 µg	60 I.U. or 18 µg	180 I.U. or 54 µg
Vitamin D	expressed as retinol 40 I.U. or 1 µg	expressed as retinol 120 I.U. or 3 µg	expressed as retinol 10 I.U. or 0.25 µg	expressed as retinol 30 I.U. or 0.75 µg
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	45 µg	N.S. ¹	11 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	0.15 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
3.2.5 Vitamin E (α-tocopherol compounds)	0.7 I.U./g linoleic acids, but in no case less than 0.7 I.U./100 available calories	N.S. ¹	0.7 I.U./g linoleic acids, but in no case less than 0.15 I.U./100 available kilojoules	

3.2.6 Minerals

Sodium (Na)	20 mg	85 mg	5 mg	21
mg				
Potassium (K)	80 mg	N.S. ¹	20 mg	
N.S. ¹				
Chloride (Cl)	55 mg	N.S. ¹	14 mg	
N.S. ¹				
Calcium (Ca) ⁴	90 mg	N.S. ¹	22 mg	
N.S. ¹				
Phosphorus (P) ⁵	60 mg	N.S. ²	14 mg	
N.S. ²				

¹ N.S. = Not specified

² Formulas should contain a minimum of 15 µg Vitamin B₆ per gramme of protein. See Section 3.2.1.1.

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

Magnesium (Mg)	6 mg	N.S. ¹	1.4 mg	N.S. ²
Iron (Fe)	1 mg	2 mg	0.25 mg	0.50 mg
Iodine (I)	5 µg	N.S. ²	1.2 µg	N.S. ²
Zinc (Zn)	0.5 mg	N.S. ²	0.12 mg	N.S. ²

3.3 Ingredients

3.3.1 Essential Ingredients

3.3.1.1 Follow-up formula shall be prepared from the milk of cows or of other animals and/or other protein

products of animal and/or plant origin which have been proved suitable for infants from the 6th month on and for young children and from other suitable ingredients necessary to achieve the essential composition of the product as set out in Sections 3.1 and 3.2 above.

3.3.1.2 Follow-up formula based on milk shall be prepared from ingredients as set out in Section 3.3.1.1

above except that a minimum of 3 g per 100 available Calories (or 0.7 g per 100 kilojoules) of protein shall be derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin or mineral content of the milk and which represents a minimum of 90% of the total protein.

3.3.2 Optional Ingredients

3.3.2.1 In addition to the vitamins and minerals listed under 3.2.4 to 3.2.6, other nutrients may be added when required to ensure that the product is suitable to form part of a mixed feeding scheme intended for use from the 6th month on.

3.3.2.2 The usefulness of these nutrients shall be scientifically shown.

3.3.2.3 When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children.

3.4 Purity Requirements

3.4.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants from the 6th month on and young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.

¹ N.S. = Not specified

3.4.2 Vitamin Compounds and Mineral Salts

3.4.2.1 Vitamin compounds and mineral salts used in accordance with Sections 3.3.1 and 3.3.2 should be selected from the Advisory Lists for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children approved by the Codex Alimentarius Commission (CAC/GL 10-1979).

3.4.2.2 The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.2.6.

3.5 Consistency and Particle Size

When prepared according to the directions for use, the product shall be free of lumps and of large, coarse particles.

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:

	Maximum Level in 100 ml of Product Ready-for-Consumption
4.1 Thickening Agents	
4.1.1 Guar gum	} 0.1 g
4.1.2 Locust bean gum	}
4.1.3 Distarch phosphate	} 0.5 g singly or in
4.1.4 Acetylated distarch phosphate	} combination in soy-based
4.1.5 Phosphated distarch phosphate	}
4.1.6 Acetylated distarch Adipate	} 2.5 g singly or in } combination in hydrolyzed } protein and/or amino acid-

4.1.7 Carrageenan	} based products only } 0.03 g singly or in } combination in milk and soy- } based products only }
4.1.8 Pectins	} 0.1 g singly or in } combination in hydrolyzed } protein and/or amino acid- } based liquid products only 1 g

**Maximum Level in 100 ml of
Product Ready-for-Consumption**

4.2 Emulsifiers

4.2.1 Lecithin	0.5 g
4.2.2 Mono- and Diglycerides	0.4 g

4.3 pH-Adjusting Agents

4.3.1 Sodium hydrogen carbonate	}
4.3.2 Sodium carbonate	}
4.3.3 Sodium citrate	}
4.3.4 Potassium hydrogen carbonate }	}
4.3.5 Potassium carbonate	} Limited by Good
4.3.6 Potassium citrate	} Manufacturing Practice
4.3.7 Sodium hydroxide	} within the limits for sodium in
4.3.8 Potassium hydroxide	} Section 3.2.6
4.3.9 Calcium hydroxide	}
4.3.10 L (+) Lactic acid	}
4.3.11 L (+) Lactic acid producing cultures	}
4.3.12 Citric acid	}

4.4 Antioxidants

4.4.1 Mixed tocopherols concentrate	} 3 mg singly or in } combination
4.4.2 α -Tocopherol	}
4.4.3 L-Ascorbyl palmitate	} 5 mg singly or in
4.4.4 L-Ascorbic acid and	} combination, expressed as

its Na, Ca salts } ascorbic acid (see Section 3.2.6)

4.5 Flavours

4.5.1 Natural Fruit Extracts	GMP
4.5.2 Vanilla extract	GMP
4.5.3 Ethyl vanillin	5 mg
4.5.4 Vanillin	5 mg

4.6 Carry-Over Principle

Section 3 of the "Principle Relating to the Carry-Over of Food Additives into Foods" as set forth in Codex Alimentarius Volume 1, shall apply.

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 relevant provisions of 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 CONTAINERS

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 1/2 oz.);

(ii) not less than 85% v/v for products in the weight range 150-250 g (5 1/2 - 9 oz.); and

(iii) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

9. LABELLING

The following specific provisions are apply for labelling of pre-packed food:

9.1 The Name of the Food

9.1.1 The name of the food shall be "Follow-up Formula". In addition thereto, any appropriate designation may be used in accordance with national usage.

9.1.2 Those products which are prepared from whole or skimmed milk in accordance with Section 3.3.1.2 and where 90% or more of the protein is derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin and mineral content of the milk, may be labelled "Follow-up Formula based on milk".

9.1.3 All sources of protein shall be clearly shown on the label in close proximity to the name of the food in descending order of proportion by weight.

9.1.4 A product which contains neither milk nor any milk derivative may be labelled "contains no milk or milk products" or an equivalent phrase.

9.2 List of Ingredients

The declaration of the list of ingredients shall be in accordance with Sections 4.2.1, 4.2.2 and 4.2.3 of the Codex General Standard for the Labelling of Prepackaged Foods 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.

9.3 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) per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption.
- (b) The number of grammes of protein, carbohydrate and fat per 100 g 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.
- (c) The total quantity of each vitamin, mineral and any optional ingredient, as listed in Section 3.3.2 of this standard per 100 g 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

In addition to the declaration of date marking and storage instructions in accordance with Sections 4.7.1 and 4.7.2 of the Codex General Standard for the Labelling of Prepackaged Foods, the following provisions apply:

9.4.1 Storage of Opened Food

Storage instructions of opened packages of a food for special dietary uses shall be included on the label if necessary to ensure that the opened product maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening.

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.

9.5.2 The labelling of a Follow-up Formula shall include a statement that Follow-up Formula shall not be introduced before the 6th month of life.

9.5.3 Information that infants and children fed Follow-up Formula shall receive other foods in addition to the food shall appear on the label.

9.6 Additional Requirements

The products covered by this standard are not breast-milk substitutes and shall not be presented as such.

10. METHODS OF ANALYSIS AND SAMPLING

Pakistan Standard Specification for processed cereal- based food for Infants

1. SCOPE

This standard covers processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).

2. DESCRIPTION

Processed cereal-based foods are prepared primarily from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis.

2.1. PRODUCT DEFINITIONS

Four categories are distinguished:

2.1.1 Products consisting of cereals which are or have to be prepared for consumption with milk or other appropriate nutritious liquids;

2.1.2 Cereals with an added high protein food which are or have to be prepared for consumption with water or other appropriate protein-free liquid;

2.1.3 Pasta which are to be used after cooking in boiling water or other appropriate liquids;

2.1.4 Rusks and biscuits which are to be used either directly or, after pulverization, with the

addition of water, milk or other suitable liquids.

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 young children means persons from the age of more than 12 months up to the age of three years (36 months).

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 ESSENTIAL COMPOSITION

3.1.1 The four categories listed in 2.1.1 to 2.1.4 are prepared primarily from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat. They may also contain legumes (pulses), starchy roots (such as arrow root, yam or cassava) or starchy stems or oil seeds in smaller proportions.

3.1.2 The requirements concerning energy and nutrients refer to the product ready for use as marketed or prepared according to the instructions of the manufacturer, unless otherwise specified.

3.2 ENERGY DENSITY

The energy density of cereal-based foods should not be less than 3.3 kJ/g (0.8 kcal/g).

3.3 PROTEIN

3.3.1 The chemical index of the added protein shall be equal to at least 80% of that of the reference protein casein or the Protein Efficiency Ratio (PER) of the protein in the mixture shall be equal to at least 70% of that of the reference protein casein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose. Only natural forms of L-amino acids should be used.

3.3.2 For products mentioned in points 2.1.2 and 2.1.4, the protein content shall not exceed 1.3 g/100 kJ (5.5 g/100 kcal).

3.3.3 For products mentioned in point 2.1.2 the added protein content shall not be less than 0.48 g/100 kJ (2 g/100 kcal).

3.3.4 For biscuits mentioned in point 2.1.4 made with the addition of a high protein food, and presented as such, the added protein shall not be less than 0.36 g/100 kJ (1.5 g/ 100 kcal).

3.4 CARBOHYDRATES

3.4.1 If sucrose, fructose, glucose, glucose syrup or honey are added to products mentioned in points 2.1.1 and 2.1.4:

- the amount of added carbohydrates from these sources shall not exceed 1.8 g/100 kJ (7.5 g/100 kcal);

- the amount of added fructose shall not exceed 0.9 g/100 kJ (3.75 g/100 kcal).

3.4.2 If sucrose, fructose, glucose, glucose syrup or honey are added to products mentioned in point 2.1.2:

- the amount of added carbohydrates from these sources shall not exceed 1.2 g/100 kJ (5 g/100 kcal);
- the amount of added fructose shall not exceed 0.6 g/100 kJ (2.5 g/100 kcal).

3.5 LIPIDS

3.5.1 For products mentioned in point 2.1.2 the lipid content shall not exceed 1.1g/100 kJ (4.5 g/100 kcal). If the lipid content exceeds 0.8g/100kJ (3.3g/100kcal):

- the amount of linoleic acid (in the form of triglycerides=linoleates) shall not be less than 70 mg/100 kJ (300 mg/100 kcal) and shall not exceed 285 mg/100 kJ (1200 mg/100 kcal);
- the amount of lauric acid shall not exceed 15% of the total lipid content;
- the amount of myristic acid shall not exceed 15% of the total lipid content.

3.5.2 Product categories 2.1.1 and 2.1.4 shall not exceed a maximum lipid content of 0.8 g /100 kJ (3.3 g/100 kcal).

3.6 MINERALS

3.6.1 The sodium content of the products described in Sections 2.1.1 to 2.1.4 of this Standard shall not exceed 24 mg/100 kJ (100 mg/100 kcal) of the ready-to-eat product.

3.6.2 The calcium content shall not be less than 20 mg/100 kJ (80 mg/100 kcal) for products mentioned in points 2.1.2.

3.6.3 The calcium content shall not be less than 12 mg/100 kJ (50 mg/100 kcal) for products mentioned in point 2.1.4 manufactured with the addition of milk and presented as such.

3.7 VITAMINS

3.7.1 The amount of vitamin B1 (thiamin) shall not be less than 12.5µg/100 kJ (50µg/100 kcal).

3.7.2 For products mentioned in 2.1.2, the amount of vitamin A and vitamin D shall be within the following limits:

	µg/100kJ	µg/100kcal
vitamin A (µg retinol equivalents)	14-43	60 – 180

vitamin D	0.25-0.75	1 – 3
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These limits are also applicable to other processed cereal-based foods when vitamin A or D are added.

3.7.3 Reductions of the maximum amounts for vitamin A and Vitamin D referred to in 3.7.2 and the addition of vitamins and minerals for which specifications are not set above shall be in conformity with the legislation of the country in which the product is sold.

3.7.4 Vitamins and/or minerals added 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).

3.8 OPTIONAL INGREDIENTS

3.8.1 In addition to the ingredients listed under 3.1, other ingredients suitable for infants who are more than six months of age and for young children can be used.

3.8.2 Products containing honey or maple syrup should be processed in such a way as to destroy

spores of *Clostridium botulinum*, if present.

3.8.3 Only L(+) lactic acid producing cultures may be used.

3.9 FLAVOURS

The following flavours may be used:

- Natural fruit extracts and vanilla extract: GMP
- Ethyl vanillin and vanillin: 7 mg/100 g RTU

3.10 QUALITY FACTORS

3.10.1 All ingredients, including optional ingredients, shall be clean, safe, suitable and of good quality.

3.10.2 All processing and drying should be carried out in a manner that minimizes loss of nutritive value, particularly protein quality.

3.10.3 The moisture content of the products shall be governed by good manufacturing practice for the individual product categories and shall be at such a level that there is a minimum loss of nutritive value and at which microorganisms cannot multiply.

3.11 CONSISTENCY AND PARTICLE SIZE

3.11.1 When prepared according to the label directions for use, processed cereal-based foods should have a texture appropriate for the spoon feeding of infants or young children of the age for which the product is intended.

3.11.2 Rusks and biscuits may be used in the dry form so as to permit and encourage chewing or they may be used in a liquid form, by mixing with water or other suitable liquid, that would be similar in consistency to dry cereals.

3.12 SPECIFIC PROHIBITION

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

The use of partially hydrogenated fats for these products is prohibited.

4. FOOD ADDITIVES

Only the food additives listed in this Section or in the Codex Advisory List of Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

- a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and
- b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CODEX/STAN 192-1995).

The following additives are permitted in the preparation of processed cereal-based foods for infants and young children, as described in Section 2.1 of this Standard (in 100 g of product, ready for consumption prepared following manufacturer's instructions unless otherwise indicated).

INS no.		Maximum level
Emulsifiers		
322	Lecithins	1500 mg
471	Mono- and diglycerides	
472a		
472b	Acetic and fatty acid esters of glycerol	500 mg Singly or in combination
472c	Citric and fatty acid esters of glycerol	

Acidity Regulators		
500 ii	Sodium hydrogen carbonate	GMP
501 ii	Potassium hydrogen carbonate	GMP
170 i	Calcium carbonate	GMP
270	L(+) Lactic acid	GMP
330	Citric acid	GMP
260	Acetic acid	GMP
261	Potassium acetate	
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	
331 i	Monosodium citrate	
331 ii	Trisodium citrate	
332 i	Monopotassium citrate	

332 ii	Tripotassium citrate	GMP 500 mg Singly or in combination	
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		
335 i	monosodiumtartrate		
335ii	Disodium tartrate		
336 i	Monopotassium tartrate – L(+)form only		
336 ii	Dipotassium tartrate – L(+)form only		Tartrates as residue in biscuits and rusks
337	Potassium sodium L(+) tartrate L(+)form only		

338	Orthophosphoric acid	Only for pH adjustment 440 mg Singly or in combination as phosphorous
339 i	Monosodium orthophosphate	
339 ii	Disodium orthophosphate	
339 iii	Trisodium orthophosphate	
340 i	Monopotassium orthophosphate	
340 ii	Dipotassium orthophosphate	
340 iii	Tripotassium orthophosphate	
341i	Monocalcium orthophosphate	
341ii	Dicalcium orthophosphate	
341iii	Tricalcium orthophosphate	
Antioxidants		
306	Mixed tocopherols concentrate	300 mg/kg fat or oil basis, Singly or in combination
307	Alpha-tocopherol	
304	L-Ascorbyl palmitate 200 mg/kg fat	200 mg/kg fat
300	L-Ascorbic acid	50 mg, expressed
301	Sodium ascorbate	

		ascorbic acid
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 2000 mg in gluten-free cereal-based foods
412	Guar gum	
414	Gum arabic	
415	Xanthan gum	
440	Pectins (Amidated and Non-Amidated)	

1404	Oxidized starch	5000 mg Singly or in combination
1410	Monostarch phosphate	
1412	Distarch phosphate	
1413	Phosphated distarch phosphate	
1414	Acetylated distarch phosphate	
1422	Acetylated distarch adipate	
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

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.

These measures shall take into account the specific nature of the products concerned and the specific population group for which they are intended.

5.2 OTHER CONTAMINANTS

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.

6. HYGIENE

It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principle of Hygiene (CAC/RCP 1 1969), Recommended International Codex of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

The product should comply with any microbiological criteria established in accordance with the Principles for the Establishment and application of microbiological Criteria for Foods (CAC/GL 21-1997).

7. PACKAGING

7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food.

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

8. LABELLING

8.1.1 The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the

Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) apply to this standard. With specific reference to section 7 of the Codex General Standard for the Labelling of Prepackaged Foods national jurisdictions may further restrict the use of pictorial devices.

8.1.2 Taking into account paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims, nutrition claims may be permitted under national legislation for the foods that are the subject of the standard provided that they have been demonstrated in rigorous studies with adequate scientific standards.

8.1.3 Any indication required in the labelling should be made in the appropriate language(s) of the country in which the product is sold.

8.2 THE NAME OF THE FOOD

The name of the food shall be "Dry Cereal for Infants (and/or Young Children)", "Rusks for Infants (and/or Young Children)" or "Biscuits (or "Milk Biscuits") for Infants (and/or Young Children)" or "Pasta for Infants (and/or Young Children)", or any appropriate designation indicating the true nature of the food, in accordance with national legislation.

8.3 LIST OF INGREDIENTS

8.3.1 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 minerals, these may 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.

8.3.2 The specific name shall be declared for ingredients and food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.

8.4 DECLARATION OF NUTRITIVE VALUE

8.4.1 The declaration of nutrition information shall contain the following information which should be in the following order:

(a) The energy value, expressed in kilocalories (kcal) and kilojoules (kJ), and the amount of protein, carbohydrate and fat expressed in grammes (g) per 100 g or 100 ml of the food as sold, and where appropriate, as per specified quantity of the food as suggested for consumption;

(b) The average amount of each vitamin and mineral for which specific levels are defined in section 3.6 and 3.7 expressed in numerical form per 100g or 100 ml of the food as sold and, where appropriate, as per specified quantity of the food as suggested for consumption;

(c) Any other nutritional information required by national legislation.

8.4.2 The labelling may bear the average amount of the vitamins and minerals when their declaration is not covered by the provisions of section 8.4.1 (b) expressed in numerical form per 100g or 100 ml of the product as sold and, where appropriate, per specified quantity of the food as suggested for consumption.

8.5 DATE MARKING AND STORAGE INSTRUCTIONS

8.5.1 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.

8.5.2 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.

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

8.6 INFORMATION FOR UTILIZATION

8.6.1 Directions as to the preparation and use of the food, and its storage and keeping before

and after the container has been opened, shall appear on the label and may also appear on the accompanying leaflet.

8.6.2 For products covered by 2.1.1, directions on the label shall state “Milk or formula but no water shall be used for dilution or mixing” or an equivalent statement.

8.6.3 When the product is composed of gluten-free ingredients and food additives, the label may show the statement “gluten-free”¹.

8.6.4 The label shall indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product. In addition, the label shall include a statement indicating that the decision when precisely to begin complementary feeding, including any exception to six months of age, should be made in consultation with a health worker, based on the individual infant’s specific growth and development needs. Additional requirements in this respect may be made in accordance with the legislation of the country in which the product is sold.

8.7 ADDITIONAL REQUIREMENTS

The products covered by this standard are not breast-milk substitutes and shall not be presented as such.

9. METHODS OF ANALYSIS AND SAMPLING

See Section on methods in the Standard for Infant Formula.

In addition:

Detection of Irradiated Foods

Codex General Methods.

¹ Codex Standard for Gluten-Free Foods (118-1981).