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DRAFT EAST AFRICAN STANDARD

Infant formula — Specification

EAST AFRICAN COMMUNITY

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Copyright notice

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Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standards.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC 018, Nutrition and foods for special dietary uses.

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights.

This third edition cancels and replaces the first edition (EAS 4: 2013), which has been technically revised.

Introduction

This Draft East African Standard gives guidelines on the formulation of infant food manufactured to substitute human milk. This standard covers safety and quality requirements, methods of sampling and test.

Due to time and career constraints, there is every possibility for mothers to resort to the use of infant food formula for the sake of convenience to substitute breast-feeding. It should be emphasized that breast-feeding is the best and safest mode of bringing up strong healthy babies. The first weeks of an infant's life are especially important in that mother's milk containing colostrums is considered necessary for proper development of the infant's defence mechanism.

The use of infant food formula preparation should be understood in its proper perspective. The formula is a supplementary food for infants up to the age of 12 months. In unavoidable situations where mother's milk is not available, the formula can be used as the sole source of nourishment up to the age of six months. In order to get the best possible benefits from infant food formula, mothers should consult health professionals for advice and acquaint themselves fully with the manufacturer's instructions in connection with proper feeding procedures, cleaning and sterilization procedures for feeding utensils and hygienic preparation of the formula.

Infant formula — Specification

1 Scope

This Draft East African Standard specifies the requirements sampling and test methods for infant formula in liquid or powdered form intended for use, where necessary, as a substitute for breast milk in meeting the normal nutritional requirements of infants.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

AOAC 952.20, *Cobalamin (Vitamin B12 Activity) in vitamin preparations — Microbiological methods*

AOAC 970.65, *Riboflavin (Vitamin B2) in foods and vitamin preparations — Fluorometric method*

AOAC 984.26, *Vitamin C (Total) in food — Semi-automated fluorometric method*

AOAC 984.27, *Calcium, Copper, Iron, Magnesium, Manganese, Phosphorus, Potassium, Sodium, and Zinc in Infant Formula — Inductively Coupled Plasma Emission Spectroscopic method*

AOAC 985.35, *Minerals in Infant Formula, Enteral Products, and Pet Foods — Atomic Absorption Spectrophotometric method*

AOAC 986.24, *Phosphorus in infant formula and enteral products — Spectrophotometric method*

AOAC 986.26, *Chloride in milk based infant formula — Protentiometric method*

AOAC 986.27, *Thiamine (Vitamin B1) milk based infant formula — Flurometric method*

AOAC 992.04, *Vitamin A (Retinol isomers) in milk and milk-based infant formula — Liquid chromatographic method*

AOAC 992.05, *Total folate (pteroylglutamic acid) in infant formula — Microbiological methods*

AOAC 992.07, *Pantothenic Acid in milk based infant formula — Microbiological turbidimetric method*

AOAC 992.24, *Iodide in ready-to-feed milk-based infant formula — Ion-selective electrode method*

AOAC 992.26, *Vitamin D3 (Cholecalciferol) in ready to feed milk based infant formula – Liquid chromatography method*

AOAC 999.11*, Lead, Cadmium, Copper, Iron, and Zinc in foods – Atomic absorption Spectrophotometry after dry ashing*

AOAC 999.14, *Isolated trans unsaturated fatty acid content in partially hydrogenated fats — Infrared spectrophotometric method*

AOAC 999.15, *Vitamin K in milk and infant formula – Liquid chromatography method*

AOAC 2004.07, *Vitamin B6 in reconstituted infant formula – Liquid chromatography method*

AOAC 2012.12, *Analysis of free and total myo-inositol in infant formula by HPAEC-PAD (High Performance Anion Exchange Chromatography With Pulsed Amperometric Detection)*

CAC/RCP 66, *Code of hygienic practice for powdered formulae for infants and young children*

CODEX STAN 192*, General standard for food additives*

EAS 38, *General standard for the labelling of pre-packaged foods*

EAS 39*, Hygiene in the food and drink manufacturing industry — Code of practice*

ISO 8070, *Milk and milk products — Determination of calcium, sodium, potassium and magnesium contents — Atomic Absorption Spectrometric Method*

ISO 20649, *Infant formula and adult nutritionals — Determination of chromium, selenium and molybdenum — Inductively coupled plasma mass spectrometry (ICP-MS)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
infant
person not more than 12 months of age

3.2
infant formula
breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first six months of life up to the introduction of appropriate complementary feeding

3.3
calorie
kilocalorie or ‘large calorie’ (1 kilo joule is equivalent to 0.239 kilocalorie)

3.4
complementary foods
food other than breast milk or infant formula whether manufactured or locally prepared and fed to older infants and young children in addition to breast milk or to infant formula when either becomes insufficient to satisfy their nutritional requirements

3.5
young children
person from the age of more than 12 months up to the age of three years (36 months)

4 Requirements

4.1 General requirements

4.1.1 The product shall be nutritionally adequate to promote normal growth and development when used in accordance with the directions for use on the label. 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.

4.1.2 The product shall be processed by physical means only and packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.

4.1.3 When prepared according to the directions for use on the label, the product shall be free of lumps and of large coarse particles and suitable for adequate feeding of infants.

NOTE The nutritional safety and adequacy of infant formula should be scientifically demonstrated to support growth and development of infants.

4.2 Specific requirements

4.2.1 Ingredients

4.2.1.1 Infant formula shall be based on milk from dairy animals and/or other edible constituents of animals including fish, or plant origin, which have been proven to be suitable for infant feeding.

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

4.2.1.3 All ingredients and food additives shall be gluten-free.

4.2.2 Energy

Infant formula prepared ready for consumption in accordance with the directions for use on the label shall contain per 100 mL not less than 60 kcal (250 kJ) and not more than 70 kcal (295 kJ) of energy.

4.2.3 Proteins

4.2.3.1 The minimum value of protein for infant formula based on cows' milk shall be 1.8 g/100 kcal or 0.45 g/100 kJ and the maximum value shall be 3.0 g/100 kcal or 0.7 g/100 kJ. 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.

NOTE The calculation of the protein content of the final product prepared ready for consumption is based on N x 6.25. The conversion factor for protein content is 6.25 for formula based on cows' milk. The conversion factor for protein content is 6.38 for formula based on non-cows' milk. The conversion factor for protein content is 5.71 for formula based on soy products. Scientific justification may be provided for the use of a different conversion factor for a particular product.

4.2.3.2 For an equal energy value, the formula shall contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein; 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 shall be demonstrated by clinical testing.

4.2.3.3 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.

4.2.3.4 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 shall be clinically evaluated.

4.2.4 Lipids

4.2.4.1 The minimum value of lipids for infant formula shall be 4.4 g/100 kcal or 1.05 g/100 kJ and the maximum value shall be 6.0 g/100 kcal or 1.4 g/100 kJ.

4.2.4.2 Lauric and myristic acids as constituents of fats, in combination, shall not exceed 20 % of total fatty acids.

4.2.4.3 The content of trans fatty acids shall not exceed 3 % of total fatty acids.

NOTE 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.

4.2.4.4 The erucic acid content shall not exceed 1 % of total fatty acids.

4.2.4.5 The total content of phospholipids shall not exceed 300 mg/100 kcal or 72 mg/100 kJ.

4.2.4.6 The total content of Linoleic acid shall be not less than 300 mg/100 kcal or 72 mg/100 kJ and not more than 1400 mg/100 kcal or 330 mg/100 kJ.

4.2.4.7 The total content of α-Linolenic acid shall be not less than 50 mg/100 kcal or 12 mg/100 kJ. The maximum content for α-Linolenic acid is not specified.

4.2.4.8 The ratio of Linoleic/α-Linolenic acid shall be a minimum of 5:1 and a maximum of 15:1.

4.2.5 Carbohydrates

4.2.5.1 The minimum value of total carbohydrates for infant formula shall be 9.0 g/100 kcal or 2.2 g/100 kJ and the maximum value shall be 14.0 g/100 kcal or 3.3 g/100 kJ.

4.2.5.2 Lactose and glucose polymers shall be used as the main source of carbohydrates for infant formula based on cows' milk protein and hydrolyzed protein. Only pre-cooked and/or gelatinized starches gluten-free by nature may be added to infant formula up to 30 % of total carbohydrates and up to 2 g/100 mL.

4.2.5.3 Sucrose shall not be used in infant formula, unless scientific justification is provided.

4.2.5.4 Fructose as an ingredient shall not be used in infant formula because of potential life-threatening symptoms in young infants with unrecognized hereditary fructose intolerance.

4.2.6 Vitamins and minerals

4.2.6.1 Vitamins, minerals and other nutrients added shall be selected from CAC/GL 10. Infant formula shall contain, per 100 calories (and 100 kilojoules) of intake, not less than the minimum and not more than the maximum levels of vitamins and minerals as specified in Table 1.

Table 1 — Limits of vitamins and minerals in infant formula

Vitamin	Amounts per 100 calories		Amounts per 100 kilojoules		Test method
	Minimum	Maximum	Minimum	Maximum	
Vitamin A	60 µg RE[a]	180 µg RE	14 µg RE	43 µg RE	AOAC 992.04
Vitamin D_3 (Cholecalciferol)	1 µg [b]	2.5 µg	0.25 µg	0.6 µg	AOAC 992.26
Vitamin C (Ascorbic acid)	10 mg	NS[c]	2.5 mg	NS [c]	AOAC 984.26

Vitamin.B_1 (Thiamine)	60 µg	NS[c]	14 µg	NS [c]	AOAC 986.27
Vitamin. B_2 (Riboflavin)	80 µg	NS[c]	19 µg	NS [c]	AOAC 970.65
Vitamin B_6[d]	35 µg	NS[c]	8.5 µg	NS [c]	AOAC 2004.07
Folic acid	10 µg	NS[c]	2.5 µg	NS [c]	AOAC 992.05
Pantothenic acid	400 µg	NS[c]	96 µg	NS [c]	AOAC 992.07
Vitamin B_{12}	0.1 µg	NS[c]	0.025 µg	NS [c]	AOAC 952.20
Vitamin K_1	4 µg	NS[c]	1.0 µg	NS [c]	AOAC 999.15
Vitamin H (Biotin)	1.5 µg	NS[c]	0.4 µg	NS [c]	EN 15607
Vitamin E (a-tocopherol compounds)	0.5 mg α-TE[e]		0.12 mg α-TE	NS [c]	AOAC 992.03

[a] 1 µg RE = 3.33 IU (International Units) Vitamin A

[b] 1 µg Cholecalciferol = 40 IU (International Units) Vitamin D_3

[c] NS = Not Specified.

[d] Formula with a higher protein content than 1.8 g protein/100 calories shall contain a minimum of 15 microgram Vitamin B_6 per gram of protein.

[e] Or per gram polyunsaturated fatty acids, expressed as Linoleic acid.

Minerals	Minimum	Maximum	Minimum	Maximum	Test method
Sodium (mg)	20	60	5	14	AOAC 984.27
Potassium (mg)	60	180	14	43	AOAC 984.27
Chloride (mg)	50	160	12	38	AOAC 986.26
Calcium [a)] (mg)	50	NS	12	NS	ISO 8070
Phosphorus[a] mg	25	NS	6	NS	AOAC 986.24
Magnesium (mg)	5	NS	1.2	NS	ISO 8070
Iron (mg)[b]	0.45	NS	0.1	NS	AOAC 999.11
Iodine (µg)	10	NS	2.5	NS	AOAC 992.24
Copper (µg)[c]	35	NS	8.5	NS	AOAC 985.35
Zinc (mg)[c]	0.5	NS	0.12	NS	AOAC 985.35
Manganese (µg)	1	NS	0.25	NS	AOAC 985.35
Selenium (µg)	1	NS	0.24	NS	ISO 20649

[a] Calcium: Phosphorus ratio shall be minimum 1:1 and maximum 2:21.

[b] Products: containing not less than 1 mg of iron/100 available calories shall be labelled “Infant formula with iron”.

[c] Zinc: copper ratio shall be not less than 1:15.

NS Not Specified

4.2.6.2 Infant formula may contain other substances, per 100 calories (and 100 kilojoules) of intake, as specified in Table 2.

Table 2 —Limits of other substances in infant formula

Substance	Amounts per 100 calories		Amounts per 100 kilojoules		Test methods
	Minimum	Maximum	Minimum	Maximum	
Choline	7 mg	NS	1.7 mg	NS	AOAC 999.14

Myo-inositol	4 mg	NS	1 mg	NS	AOAC 2012.12
L-carnitine	1.2 mg	NS	0.3 mg	NS	AOAC SMPR 2012.010

4.3 Optional ingredients

4.3.1 In addition to the compositional requirements in 4.2, 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.

4.3.2 The suitability and the safety of these substances for the particular nutritional uses of infants 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.

4.3.3 Taurine may be added in amounts not exceeding 12 mg/100 kcal (3 mg/100 kJ).

4.3.4 Docosahexaenoic Acid (DHA) may be added in amounts not exceeding 0.5 % of fatty acids.

4.3.5 If docosahexaenoic acid (22:6 n-3) is added to infant formula, arachidonic acid (20:4 n-6) contents shall reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of long chain polyunsaturated fatty acid (LC PUFA), shall not exceed the content of docosahexaenoic acid.

4.4 Specific prohibition

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

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

4.4.3 Commercially hydrogenated oils and fats shall not be used in infant formulas. Products derived from genetically modified organisms shall not be used as raw material for infant formula.

5 Food additives

5.1 The food additives listed in Table 3 may be used in the preparation of infant formula.

Table 3 — List of food additives for use in infant formula

Additive	Maximum level in 100 mL of the ready-to-drink product
Thickening agents	
Guar gum	0.1 g in liquid formulas containing hydrolyzed protein
Locust bean gum	0.1 g in all types of infant formula
Distarch Phosphate	0.5 g singly or in combination with soya-based infant formula only
Acetylated distarch prosphate	
Phosphated distarch phosphate	2.5 g singly or in combination in hydrolyzed protein and/or amino acid based infant formula only
Hydroxypropyl starch	
Carrageenan	0.03 g in regular milk-and soy-based liquid infant formula only 0.1 g in hydrolyzed protein- and/or amino acid based liquid infant formula only
Emulsifiers	
Lecithin	0.5 g in all types of infant formula

Mono-and di-glyceride	0.4 g in all types of infant formula
Acidity regulators	
Sodium hydroxide	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in Table 1in all types of infant formula
Sodium hydrogen carbonate	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in Table 1 in all types of infant formula
Sodium carbonate	
Potassium hydrogen carbonate	
Potassium hydroxide	
Potassium carbonate	
Calcium hydroxide	
Sodium dihydrogen citrate	Limited by GMP in all types of infant formula
Trisodium citrate	
Potassium citrate	
L (+) Lactic acid	
Citric acid	
Antioxidants	
Mixed tocopherol concentrate	1 mg in all types of infant formula singly or in combination
L-Ascorbyl Palimitate	1 mg in all types of infant formula singly or in combination
Packaging gases	
Carbon dioxide	GMP
Nitrogen	

5.2 The amount of the food additive in the raw materials or other ingredients (including food additives) shall not exceed the maximum level specified.

5.3 Any carry-over of food additives from the raw materials used shall be consistent with the provisions in the preamble of CODEX STAN 192.

6 Contaminants

6.1 Residues of pesticides, hormones and antibiotics

6.1.1 Infant formula shall comply with the maximum pesticide residue limits established by Codex Alimentarius Commission for this commodity.

6.1.2 The product shall be free from residues of hormones and antibiotics, and practically free from other contaminants especially pharmacologically active substances.

6.2 Other contaminants

Infant formula shall comply with the maximum limits for contaminants specified in table 2, when tested in accoradance with test methods therein.

Table 2 — Maximum limits for contaminants in infant formula

S/N	Contaminant	Maximum Limit	Test method

1.	Lead, mg/kg		0.02	ISO 6633
2.	Aflatoxin M1, µg/kg		0.5	ISO 14501.
3.	Melamine, mg/kg	Solid (powdered) infant formula	1.0	AOAC 2016.015
		Liquid infant formula	0.15	

7 Hygiene

7.1 Infant formula shall be prepared and packaged in the premises built and maintained under hygienic condition in accordance with EAS 39 and CAC/RCP 66.

7.2 Powdered infant formula shall conform to the microbiological limits specified in CAC/RCP 66.

8 Packaging

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

8.2 The containers, including packaging materials, shall be made only of substances, which are safe and suitable for their intended uses.

9 Fill of container

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

a) not less than 80 % v/v for products weighing less than 150 g;

b) not less than 85 % v/v for products in the weight range 150 g to 250 g; and

c) not less than 90 % v/v for products weighing more than 250 g 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.

10 Labelling

10.1 General

In addition to the requirements of EAS 38, the specific requirements in 10.2 – 10.10 shall apply and shall be legibly and indelibly marked.

10.2 The name of the food

10.2.1 The name of the product shall be either “Infant formula” or any appropriate designation indicating the true nature of the product.

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

10.2.3 The source and proportion of saturated and unsaturated fatty acids shall be indicated.

10.2.4 If 90 % or more of the protein is derived from whole or skimmed milk, as such or with minor modification, the product may be labelled “Infant formula based on milk”.

10.2.5 A product which contains neither milk nor any milk derivatives may be labelled contains no milk or milk products or an equivalent phrase.

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

10.2.7 Products containing not less than 1 mg iron (Fe) per 100 available calories shall be labelled “Infant Formula with Iron”.

10.3 List of ingredients

10.3.1 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 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.

10.3.2 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.

10.4 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 grams of protein, carbohydrate and fat per 100 grams of the foods as sold as well as per specified quantity of the food as suggested for consumption; and

b) the total quantity of each vitamin, mineral, choline and any optional ingredient as listed in 4.2.6 and 4.3 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.

10.5 Net contents

The net content of infant formula shall be declared by volume if it is in liquid form or by weight if it is in powdered form. The declaration of weight or volume shall be in metric units.

10.6 Name and address

The name and address of the manufacturer packer, distributor, importer, exporter, or vendor of the food shall be declared.

10.7 Country of origin

10.7.1 The country of origin of the food shall be declared.

10.7.2 When the food undergoes processing in a second country, which changes its nature, the latter country shall be considered the country of origin for the purpose of labelling.

10.8 Lot identification

Each container shall be embossed or otherwise permanently marked, in code or in clear, to identify the producing factory and the lot.

10.9 Date marking and storage instructions

10.9.1 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 of the year will suffice.

In the case of products requiring a declaration of monthly 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.

10.9.2 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.

10.10 Instructions for use

10.10.1 Products in liquid form may be used either directly or in the case of concentrated liquid products, shall be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use.

10.10.2 Products in powder form shall be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation.

10.10.3 Adequate directions for the appropriate preparation and use of the product, including its storage before use, after opening the container and after preparation shall be given.

A statement that formula remaining after feeding should be discarded, shall appear on the label and in any accompanying leaflet.

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

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

10.11 Additional labelling requirements

10.11.1 Labels shall not discourage breastfeeding or the use of human milk. The label shall not have any statement or information that implies that infant formula is superior to human milk or breastfeeding.

10.11.2 The trade name or any other name or information on the label shall not be similar to names of other products of different nature not intended for infants.

10.11.3 Each container label shall have a clear, conspicuous and easily readable message which includes the words "Important notice" or their equivalent, followed by:

a) a statement indicating that infant formula is intended to replace or supplement breast-feeding, where breast feeding or use of human milk is not possible or to supplement where breast milk is insufficient, may be given on the label;

b) a 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; and

d) a statement warning against the health hazards of inappropriate preparation, storage and use.

10.11.4 The label shall have no pictures, photographs, drawings, or any other graphics which represent infants and/or women other than illustrating methods of preparation. The label shall not idealize the use of infant formula.

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

10.11.5 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.

10.11.6 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.

11 Sampling

Sampling of infant formula shall be done in accordance with Annex A.

Annex A
(normative)

Sampling of infant formula

A.1 General requirements

A.1.1 In drawing, preparing, storing and handling samples, the precautions and directions in A.1.2 – A.1.6 shall be observed:

A.1.2 Samples shall be taken in a protected place not exposed to damp air, dust or soot.

A.1.3 The sampling instrument shall be clean and dry when used. When taking samples for bacteriological examination, it shall be sterile.

A.1.4 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination. The samples shall be placed in clean and dry glass containers. The sample containers shall be of such a size that they are almost completely filled by the sample. The sample containers shall in addition be sterile when they are used for samples for bacteriological examination.

A.1.5 Each container shall be sealed airtight after filling and marked with full details of sampling, batch or code number, name of the manufacturer and other important particulars of the consignment.

A.1.6 Samples shall be stored in a cool dark place and in such a manner that the temperature of the material does not vary unduly from the normal temperature.

A.2 Scale of sampling

A.2.1 All the containers in a single consignment of one type of material drawn from a single batch of manufacture shall constitute a lot. If the consignment is declared to consist of different batches of manufacture, the batches shall be marked separately and the group of containers in each batch shall constitute separate lots.

A.2.2 Samples shall be tested from each lot for ascertaining its conformity to the requirements of the relevant East African Standard.

A.2.3 The number of containers to be selected from the lot shall depend on the size of lot and shall be as given in Table 1.

Table 1 — Number of containers to be selected for sampling)

(1)	(2)	(3)
Lot size	**Number of samples (for tests other than microbiological)**	**Number of samples (for microbiological tests)**
2 to 25	2	2
26 to 100	3	3
101 to 300	5	5
301 to 500	7	7

501 and above	9	9

A.2.4 The containers shall be chosen at random from the lot, and for this purpose a random number table as agreed to between the purchaser and the supplier shall be used. If such a table is not available, the following procedure shall be adopted.

A.2.5 Starting from any container, in one order, count them as 1, 2, 3, etc., up to r and so on in a systematic manner and withdraw the rth container; r being the integral part of N/n where N is the total number of containers and n the number of containers to be selected according to column 2 or 3 of Table 1.

A.3 Test samples and referee samples

A.3.1 Microbiological examination samples

Sampling for microbiological examination shall be carried out before sampling for chemical analysis.

A.3.2 Preparation of individual sample

Draw with a suitable sampling instrument approximately equal quantities of the material from different parts of the container till about 500 g of the material are obtained. From this, take about 150 g of the material and divide it into three equal parts. Each part so obtained shall constitute an individual sample representing the container and shall be transferred immediately to thoroughly clean and dry containers sealed air-tight with particulars given under A.1.5. The individual sample so obtained shall be divided into three sets in such a way that each set has a sample, representing each selected container. One of these shall be marked for the purchaser, another for the vendor and the third for the referee.

A.3.3 Preparation of composite sample

From the material from each selected container, remaining after the individual sample has been taken, approximately equal quantities of the material shall be taken and mixed together so as to form a composite sample weighing about 600 g. This composite sample shall be divided into three equal parts and transferred to clean and dry containers, sealed airtight and labelled with the particulars given in A.1.5. One of these composite samples shall be for the purchaser, another for the vendor and the third for the referee. Sufficient care shall be taken during the preparation of composite sample to avoid contamination.

A.3.4 Preparation of samples for microbiological examination

From the selected containers select a sub-sample according to column 3 of Table 1. Draw with a suitable sampling instrument, which is sterile, at least 100 g of the material and mix thoroughly under aseptic conditions to form a sample of container for microbiological examination. Divide the sample (taking care not to bring in microbiological contamination in the material) into three equal parts. Each part so obtained shall constitute a sample representing the container and shall be transferred to sterile glass containers, sealed air-tight and labelled with particulars given in A.1.5. They shall be marked, in addition with the words, 'For Microbiological Examination'. The samples so obtained shall be divided into three sets in such a way that each set has a sample representing each selected container. One of these sets shall be marked for the purchaser, another for the vendor and the third for the referee.

A.3.5 Referee samples

Referee samples shall consist of a set of individual samples (A.3.2), a composite sample (A.3.3) and a set of samples for microbiological examination (A.3.4) marked for this purpose and shall bear the seals of the purchaser and the vendor. These shall be kept at a place as agreed to between the two parties.

A.4 Number of tests

A.4.1 Test for the determination of moisture, flavour and fat shall be conducted on each of the samples constituting a set of individual samples.

A.4.2 Tests for the determination of acid-insoluble ash, Vitamin A, added Vitamin D and iron total carbohydrate, and total milk protein shall be conducted on the composite sample.

A.4.3 Test for bacterial count and coliform count shall be conducted on each of the samples constituting a set of test samples labelled with the words ‘For Microbiological Examination'.

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 breast 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 breast milk or infant formula that complies with description of foods for special medical purposes 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 Foods for special medical purposes are a category of foods for special dietary uses which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.

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.

2.1.4 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 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

Vitamins and minerals added in accordance be selected from the *Advisory Lists of Mineral Salts and Vitamin Compounds* for *Use in Foods for Infants and Children* (CAC/GL 10-1979).

3.4 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 adequate feeding of young infants.

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 Prohibitions

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

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

3.6.3 Commercially hydrogenated oils and fats shall not be used in infant formulas. Products derived from genetically modified organisms shall not be used as raw material for infant formula.

5 Food additives

5.1 The food additives listed in Table 3 may be used in the preparation of infant formula for special medical purposes.

Table 3 — List of food additives for use in infant formula for special medical purposes

Additive	Maximum level in 100 mL of the ready-to-drink product
Thickening agents	
Guar gum	0.1 g in liquid formulas containing hydrolyzed protein
Locust bean gum	0.1 g in all types of infant formula
Distarch Phosphate	0.5 g singly or in combination with soya-based infant formula only
Acetylated distarch prosphate	
Phosphated distarch phosphate	2.5 g singly or in combination in hydrolyzed protein and/or amino acid based infant formula only
Hydroxypropyl starch	
Carrageenan	0.03 g in regular milk-and soy-based liquid infant formula only 0.1 g in hydrolyzed protein- and/or amino acid based liquid infant formula only
Emulsifiers	
Lecithin	0.5 g in all types of infant formula
Mono-and di-glyceride	0.4 g in all types of infant formula
Acidity regulators	
Sodium hydroxide	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in Table 1in all types of infant formula
Sodium hydrogen carbonate	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in Table 1 in all types of infant formula
Sodium carbonate	
Potassium hydrogen carbonate	
Potassium hydroxide	
Potassium carbonate	
Calcium hydroxide	
Sodium dihydrogen citrate	Limited by GMP in all types of infant formula
Trisodium citrate	
Potassium citrate	
L (+) Lactic acid	
Citric acid	
Antioxidants	
Mixed tocopherol concentrate	1 mg in all types of infant formula singly or in combination
L-Ascorbyl Palimitate	1 mg in all types of infant formula singly or in combination

Packaging gases	
Carbon dioxide	GMP
Nitrogen	

5.2 The amount of the food additive in the raw materials or other ingredients (including food additives) shall not exceed the maximum level specified.

Any carry-over of food additives from the raw materials used shall be consistent with the provisions in the preamble of CODEX STAN 192.

6 Contaminants

6.1 Residues of pesticides, hormones and antibiotics

6.1.1 Infant formula shall comply with the maximum pesticide residue limits established by Codex Alimentarius Commission for this commodity.

6.1.2 The product shall be free from residues of hormones and antibiotics, and practically free from other contaminants especially pharmacologically active substances

6.2 Other contaminants

infant formula for special medical purposes shall comply with the maximum limits for contaminants specified in table 2, when tested in accoradance with test methods therein.

Table 2- Maximum limits for contaminants in infant formula for special medical purposes

S/N	Contaminant		Maximum Limit	Test method
i.	Lead, mg/kg		0.02	ISO 6633
ii.	Aflatoxin M1, µg/kg		0.5	ISO 14501
iii.	Melamine, mg/kg	Solid (powdered) infant formula	1.0	ISO/TS 15495
		Liquid infant formula	0.15	

7 Hygiene

Infant formula for special medical purposes shall be prepared and packaged in the premises built and maintained under hygienic condition in accordance with EAS 39 and CAC/RCP 66.

Powdered infant formula for special medical purposes shall conform to the microbiological limits specified in CAC/RCP 66.

8 Packaging

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

8.2 The containers, including packaging materials, shall be made only of substances, which are safe and suitable for their intended uses.

9 Fill of container

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

a) not less than 80 % v/v for products weighing less than 150 g;

b) not less than 85 % v/v for products in the weight range 150 g to 250 g; and

c) not less than 90 % v/v for products weighing more than 250 g 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.

10 Labelling

10.1 General

In addition to the requirements of EAS 38, the specific requirements in 10.2 – 10.10 shall apply and shall be legibly and indelibly marked.

10.1 The Name of the Food

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

10.1.2 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.

10.1.3 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".

10.2 List of Ingredients

10.2.1 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.

10.2.2 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.

10.3 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 *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991).

10.4 Date Marking and Storage Instructions

10.4.1 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 of the year will suffice.

In the case of products requiring a declaration of monthly 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.

10.4.2 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.

10.5 Information for Use

10.5.1 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.

10.5.2 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.

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

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

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

10.6 Additional Labelling Requirements

10.6.1 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 *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991).

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

10.6.3 In addition, the information specified in Sections 4.5.2, 4.5.3 and 4.5.6 of *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991) shall be included on the label or be provided separately from the package.

10.6.4 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.

10.6.5 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.

11 Sampling

Sampling of infant formula shall be done in accordance with Annex A.

