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EAST AFRICAN STANDARD

Ready to use therapeutic foods — Specification

EAST AFRICAN COMMUNITY

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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.

Ready to use therapeutic foods — Specification

1 Scope

This Draft East African Standard specifies requirements, sampling and test methods for Ready to use therapeutic foods (ready to eat food for people with severe and acute malnutrition from age of 6 months and above)

This standard does not apply to therapeutic milk, vitamin and mineral food supplements.

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.

AFDC 6(3869)P1 *Determination of Vitamin B2*

AFDC 6(3870)P1 *Determination of Vitamin B6*

AFDC 6(3871)P1 *Determination of Vitamin K*

AFDC 6(3872)P1 *Determination of Biotin*

AFDC 6(3873)P1 *Determination of Pantothenic acid*

AFDC 6(3874)P1 *Determination of Niacin*

AFDC 6(3875 Part 1)P2 *Determination of cadmium content (ISO 6561-1:2005) by graphite furnace atomic absorption spectrometry*

AFDC 6(3875 Part 2)P2*Determination of cadmium content (ISO 6561-2:2005) by flame atomic absorption spectrometry*

CAC/GL10 – 2008 - *Advisory list of mineral salts and vitamin compounds for use in foods for infants and children.*

TZS 109:1981- *Food processing units – code of hygiene*

TZS 118:2007 - *Microbiology of food and animal feeding stuffs – Horizontal method for enumeration of micro – organisms – Colony count technique at 30ºc*

TZS 122:2007 – *Microbiology of food and feeding stuffs – Horizontal method for the detection of salmonella spp.*

TZS 125:2002 - *Microbiology of food and animal feeding stuffs – Horizontal method for enumeration of coagulase – positive staphylococci(staphylococcus aureus and other species)*

TZS 131:2006 - *Microbiology - General guidance for enumeration of yeast and moulds – Colony count technique at 25ºc.*

TZS 1483:2012 *Infant formula-determination of total folates content by microbiological method*

TZS 1485:2012 *Infant formula determination of mineral content by atomic absorption spectrophotometric method*

TZS 1486:2012 *Infant formula-determination of phosphorus content by spectrophotometric method*

TZS 1501:2012 *Fruits and Vegetables – Determination of Mercury Content –Flameless Atomic Absorption Method*

TZS 1505:2012 *Milk based infant formula-determination of iodide content by ion selective electrode method*

TZS 1509:2012 *Milk based infant formula-determination of thiamine content by fluorometric method*

TZS 184: 1984 *Food processing units – Infant and child food – General hygiene requirements*

TZS 268: 1986 *General atomic absorption – Spectro - Photometric method for determination of lead in food stuffs*

TZS 269: 1986 *General method for estimation of ascorbic acid (Vitamin C) in food and foodstuffs*

TZS 288 (Part 2):2011 *Animal and vegetable fats and oils – Analysis by Gas Chromatography of methyl esters of fatty acids*

TZS 4:2009 - *Rounding off numerical values*

TZS 528: 1992 *General routine for determination of Vitamin A (Retinol) in food and foodstuffs*

TZS 538: 1999 *Packaging and labeling of foods*

TZS 636:2002 *General method for determination of Vitamin D in food and foodstuffs*

TZS 731:2007 / ISO 7251:2005 – *Microbiology of food and feeding stuffs – Horizontal method for detection and enumeration of presumptive Escherichia Coli – Most Probable Number Technique*

TZS 76 :2010 *General method for Determination of Arsenic silver diethyldithiocarmate photometric method*

TZS 799: 2004 *Agricultural food products– Determination of aflatoxins*

TZS 844:2006 *Peanut butter – specification*

TZS 852(Part 1):2005- *Microbiology of food and animal feeding stuffs – Horizontal method for detection and enumeration of listeria monocytogenes - Detection method (Identical to ISO 11290-1)*

TZS 852(Part 2):2005- *Microbiology of food and animal feeding stuffs – Horizontal method for detection and enumeration of listeria monocytogenes - Enumeration method (Identical to ISO 11290-2)*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
Ready-to-Use Therapeutic Food (RUTF)
high energy food contained in a concentrated form, enriched with minerals and vitamins for the treatment of people with severe acute malnutrition from age of 6 months and above. The food does not need cooking, or any other process before cooking

3.2
Severe acute malnutrition (SAM)
very low weight for height (below -3z scores of the median WHO growth standards), by visible severe wasting, or by the presence of nutritional oedema or by a mid-upper arm circumference (MUAC) less than 11.5 cm.

3.3
Malnutrition
condition that develops when the body have deficiencies or excesses in nutrient intake, imbalance of essential nutrients or impaired nutrient utilization

4 Raw Materials and ingredients

The following materials should be used in accordance with EAS relevant standards:

a) Milk and other Dairy Products;

b) Legumes and oilseeds;

c) Fats and Oils (note Partially hydrogenated fats and oils shall not be used in RUTF);.

d) Cereals, Roots and Tubers and their derived Products ;

e) Vitamins and Minerals; and

f) Carbohydrates: free sugar shall not exceed 20% of total energy; fructose and glucose shall not be used. Honey shall not be used in RUTF due to the risk of infant botulism from Clostridium botulinum

5 Requirements

5.1 General requirements

Ready-to-Use Therapeutic Food (RUTF) shall be:

a) uniform and consistent

b) free from foreign matter and extraneous matter

c) free from rancid and objectionable flavour and odour

d) soft or crushable

e) be palatable

5.2 Food Additives

Food additives may be used in the preparation of RUTF in accordance with Table 1

Table 1 —Food additives

Functional Class	Food Additive	International Numbering System (INS)	Maximum Use Level
Emulsifier	Mono- and di-glycerides of fatty acids	471	4000 mg/kg
	Citric and fatty acid es- ters of glycerol	472c	9000 mg/kg
	Lecithin	322(i)	5000 mg/kg
Antioxidant	Ascorbyl palmitate	304	10 mg/kg
	Tocopherol concentrate,mixed	307b	10 mg/kg
	Ascorbic acid, L-	300	GMP
Acidity regulator	Citric acid	330	GMP
Packaging gas	Nitrogen	941	GMP

	Carbon dioxide	290	GMP
Carrier	Silicon dioxide, amor-phous	551	10 mg/kg

5.3 Specific requirements

Ready-to-Use Therapeutic Food (RUTF) shall comply with specific requirements given in table 2 when tested in accordance with test methods specified therein.

Table 2—Compositional requirements

S/N	Component	Requirement	Test method
1.	Energy, kcal per 100grams	520 - 550	
2.	Total fat g/100 g	26 - 37	TZS 844:2006 Annex A
3.	Moisture % m/m,max	3.0	TZS 844:2006 Annex B
4.	\Dietary Fibre, % max	5	
5.	Protein , g/100 g	13-17	TZS 844:2006 Annex C
6.	Omega 6 % m/m	3 - 10	TZS 288 (Part 2):2011
7.	Omega 3% m/m	0.3 – 2.5	TZS 288 (Part 2):2011
8.	Vitamin B12 µg/100g,min	1.6	AFDC 6(3896) P1
9.	Vitamin E mg/100g,min	20 -	TZS 1508:2012
10.	Vitamin A mg/100g	0.8 – 1.6	TZS 528:1992
11.	Vitamin B1 mg/100g , min	0.5	TZS 1509:2012
12.	Vitamin B2 mg/100g,min	1.6	AFDC 6(3869) P1
13.	Vitamin B6 mg/100g,min	0.6	AFDC 6(3870) P1
14.	Vitamin C mg/100g,min	50	TZS 269:1986
15.	Vitamin D µg/100g	15 - 20	TZS 636:2002
16.	Vitamin K µg/100g	15 - 30	AFDC 6(3871) P1
17.	Biotin µg/100g ,min	60	AFDC 6(3872) P1
18.	Folic acid mg/100g , min	0.2	TZS 1483:2012
19.	Pantothenic acid mg/100g,min	3	AFDC 6(3873) P1
20.	Niacin mg/100g,min	5	AFDC 6(3874) P1
21.	Calcium mg/100g	300 785	TZS 1485:2012
22.	Phosphorus mg/100g	300 - 785	TZS 1486:2012
23.	Potassium mg/100g	1100 - 1600	TZS 1485:2012
24.	Magnesium mg/100g	80 - 235	TZS 1485:2012
25.	Zinc mg/100g	11 - 14	TZS 1485:2012
26.	Copper mg/100g	1.4 – 1.8	TZS 1485:2012
27.	Iron mg/100g	10 - 14	TZS 1485:2012
28.	Iodine µg/100g	70 - 140	TZS 1505:2012
29.	Selenium µg/100g	20 - 40	AAS
30.	Sodium mg/100g Max	290	TZS 1485:2012

6 Hygiene

6.1 The product shall be prepared under hygienic conditions in accordance with EAS39'.

6.2 The product shall not contain microbiological count more than the limit given in Table 3 below

Table 3—Microbiological limits

S/N	Microorganisms	Limit	Test methods
1.	Total Viable Count CFU/ g, max.	500	ISO 4833
2.	Coliforms CFU/ g. max.	Absent	ISO 4832
3.	*Salmonella spp* in 25 g, max.	Absent	ISO 6579-1
4.	*Escherichia Coli* CFU/ g, max.	Less than 10	ISO 16649-2
5.	*Staphylococcus aureus* CFU/ g, max.	Less than 10	ISO 6888-1
6.	*Bacillus cereus* CFU/ g, max.	Absent	ISO 7932
7.	Yeasts and moulds CFU/ g. max.	100	ISO 21527-2
8.	*Clostridium perfringens* CFU/ g. max.	Absent	ISO 7937

7 Anti-nutritional factors

7.1 If soya flour is used as a component of the RUTF, urease activity shall not exceed 0.3 mg N/g/min (for trypsin inhibitor activity, 5 mg/g) when tested in accordance with ISO 5506.

7.2 If sorghum flour is used as a component of the RUTF, the tannin content shall not exceed 0.3 % by mass on a dry matter basis when tested in accordance with ISO 9648.

7.3 If cassava is used as a component of the RUTF, the total hydrocyanic acid content shall not exceed 2 mg/kg, when tested in accordance with EAS 744.

7.4 Phytate

8 Contaminants

8.1 Mycotoxins

The product shall not contain mycotoxins more than the limit given in Table 4 below

Table 4—Mycotoxins limits

S/N	Parameters	Limits	Methods of test
1.	Total aflatoxins (B1, B2, G1, and G2), µg/kg	5	ISO 16050
2.	Aflatoxin B1, µg/kg	3	
3.	Fumonisin, mg/kg	[2]	AOAC 2001.04
4.	Ochratoxin A, µg/kg	5	ISO 15141-1
5.	Deoxynivalenol (DON), mg/kg	0.2	AOAC 986.18

8.2 Heavy metal contaminants

The level of contaminants shall conform to the limits specified in Table 5.

Table 5— Heavy metal contaminants limits

S/N	Heavy metal	Maximum limit (mg/kg)	Test method
1.	Lead	0.2	AOAC 999.11

2.	cadmium	0.1	

9 Packaging

The product shall be packed in suitable, hygienic, food grade and environmental friendly packaging materials which protect the nutritional quality and safety of the product as well as environment. The suitable packaging material shall be able to protect the product from light, oxygen, moisture and carbondioxide.

10 Labelling

In addition to the requirements of EAS 38 and EAS 803, each package shall be legibly and indelibly marked with the following:

a) name of the product as Ready to use therapeutic foods;

b) a statement that this product is not breast-milk substitute ;

c) serving/dosage instruction;

d) Statement “THE PRODUCT IS SUITABLE FOR PEOPLE WITH SEVERE AND ACUTE MALNUTRITION” from the age of six months and above shall appear on the label;

e) Not for sale; and

f) It shall be labelled in accordance with EAS 803, EAS 804.

11 Sampling

Sampling shall be done in accordance with CXG 50-2004