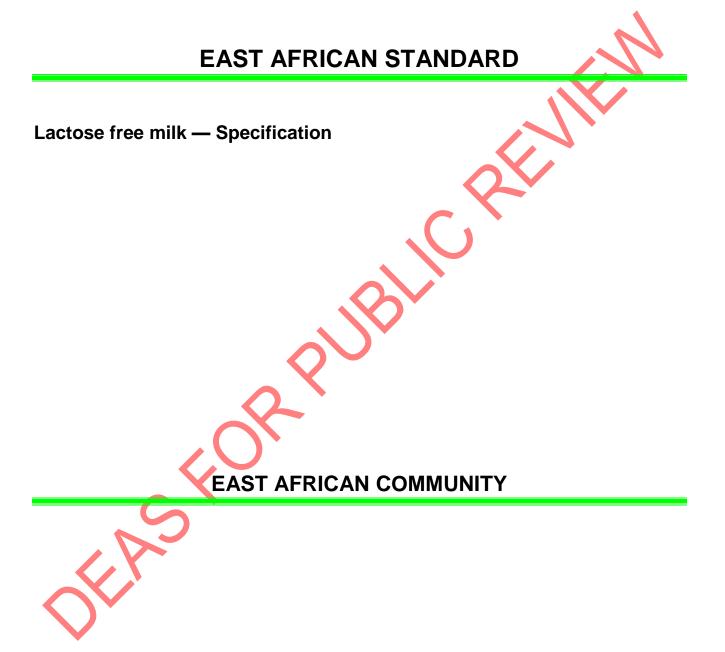
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Foreword

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 017, Milk and milk products.

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.

Lactose free milk— Specification

1 Scope

This draft East African Standard specifies the requirements, sampling and test methods for lactose free milk intended for direct human consumption or for further processing.

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 984.15, Enzymatic hydrolysis of lactose to glucose and galactose at pH 6.6 by β -galactosidase

EAS 38, Labelling of pre- packaged foods — General requirements

EAS 39, General principles for food hygiene

EAS 803, Nutrition labelling - Requirements

EAS 804, Claims on foods — General requirements

EAS 805, Use of nutrition and health claims - Requirements

ISO 11290-1, Microbiology of the food chain—Horizontal method for the detection and enumeration of Listeria monocytogenes and of Listeria spp. —Part 1: Detection method

ISO 11866-2, Milk and milk products—Enumeration of presumptive Escherichia coli—Part 2: Colony-count technique at 44 degrees C using membranes

ISO 14501, Milk and milk powder – Determination of aflatoxin M1 content — Clean-up by immunoaffinity chromatography and determination by high-performance liquid chromatography

ISO 22662, Milk and milk products — Determination of lactose content by high-performance liquid chromatography (Reference method)

ISO 4832, Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of coliforms — Colony count technique

ISO 4833-1, Microbiology of the food chain — Horizontal method for the enumeration of microorganisms — Part 1: Colony count at 30 degrees C by the pour plate technique

ISO 6579-1, Microbiology of the food chain — Horizontal method for the detection, enumeration and serotyping of Salmonella — Part 1: Detection of Salmonella spp

ISO 6731, Milk, cream and evaporated milk — Determination of total solids content (Reference method)

ISO 6888-1, Microbiology of the food chain—Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) —Part 1: Method using Baird-Parker agar medium

ISO 707, Milk and milk products — Guidance on sampling KS ISO 2446, Milk — Determination of fat content

ISO 8968-4, Milk and milk products — Determination of nitrogen content — Part 4: Determination of protein and non-protein nitrogen content and true protein content calculation (Reference method)

ISO/TS 6733, Milk and milk products—Determination of lead content—Graphite furnace atomic absorption spectrometric method

3 Terms and definitions

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

3.1

raw milk

normal, clean and fresh secretion extracted from the udder of a healthy cow

3.2

pasteurized milk

milk which has been subjected to heat treatment either by batch method, flash pasteurization or High Temperature Short Time method (HTST)

3.3

ultra high temperature (UHT) milk

milk that is treated under ultra-high temperatures, homogenized, filled and sealed aseptically into sterile retail containers in order to maintain commercial sterility under room temperatures

Note1 to entry: Commercial sterility is achieved by application of heat sufficient, alone or in combination with other appropriate treatment to render food free from microorganisms capable of growing in the food as normal non-refrigerated conditions at which the food is likely to be held during distribution and storage.

3.4

homogenized milk

the milk in which, the milk fat globules have been finely divided and interspersed to form a homogeneous product so as to prevent the fat from floating on the surface and adhering to the inside of the container

3.5

standardized milk

cow milk that has been standardized to fat and solids-not-fat percentage by the adjustment of milk solids. Standardized milk shall be pasteurized and shall show a negative alkaline phosphatase test

3.6

reconstituted milk

product resulting from the addition of water to the dried or concentrated form of the cow milk product in the amount necessary to re-establish the appropriate water to solids ratio

3.7

commercial sterility

condition achieved by application of heat sufficient, alone or in combination with other appropriate treatment to render food free from microorganisms capable of growing in the food as normal non-refrigerated conditions at which the food is likely to be held during distribution and storage

3.8

recombined milk

product resulting from the combining of milk fat and milk solids non-fat in their preserved forms with or without the addition of water to achieve the appropriate milk product composition

3.9

toned milk

product prepared by a mixture of cow milk with skimmed milk or powdered milk in the amount necessary to reestablish the appropriate milk product composition

3.10

lactose free milk

milk whose lactose content has been reduced significantly using appropriate methods.

3.11

food grade packaging material

packaging material made of substances which are safe and suitable for their intended use and which will not alter the quality, safety or organoleptic properties of the product

4 Categories of lactose free milk

lactose free milk shall be categorized as follows based on fat content:

- a) Whole/full cream;
- b) Fat reduced/semi skimmed;
- c) Low fat; and
- d) Fat free/skimmed.

5 Requirements

5.1 Raw materials

Raw materials for lactose free milk may include:

- a) raw milk;
- b) reconstituted milk;
- c) recombined milk;
- d) pasteurized milk;
- e) toned milk;
- f) standardized milk; or
- g) Lactose free powdered milk.

5.2 Optional ingredients

Lactase enzyme.

5.3 General requirements

Lactose free milk shall:

- a) have characteristic texture, flavour and colour;
- b) be free from preservatives, off-flavours and odour; and
- c) free from objectionable tastes and foreign matter.

5.4 Specific requirements

Lactose free milk shall comply with specific requirements given in Table 1 when tested in accordance with test methods specified therein.

S/N	Characteristic	Requirement	Test method
1.	[Lactose content (%), m/m, max.]	[0.1]	ISO 22662/AOAC 984.15
2.	pH Variation,max. ^a	0.3	Annex A
3.	Titratable acidity variation % lacticacid, , max. ^b	0.02	Annex B
4.	Density at 20 °C, g/ml	1.0250 – 1. 0340	Annex C
5.	Milk fat (%), m/m		ISO 2446
	a) Whole milk/full cream milk, min.	3.25	
	b) Fat reduced milk/semi skimmed	1.51 – 3.24	
	c) Low fat milk/skimmed milk	0.51 – 1.50	
	d) Fat free milk, max.	0.50	
6.	Milk solids non-fat, %, min.	7.50	ISO 6731
7.	Protein content, %, min.	3	ISO 8968-4

Table 1 — Specific requirements for lactose free milk

6 Hygiene

6.1 Lactose free milk shall be prepared and handled in accordance with accordance with EAS 39 and CXC 57

6.2 Lactose free milk shall comply with microbiological requirements given in Table 2 when tested in accordance with test methods specified therein.

Table 2 — Microbiological limits for	Lactose free milk
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S/N	Micro-organisms	Ma	Maximum limit			
		UHT Lactose free milk	Pasteurized Lactose free milk			
i.	Total Plate count, CFU/ ml	10	10 ⁴	ISO 4833-1		
ii.	Total Coliform, CFU/ ml	< 1	10	ISO 4832		
iii.	Staphylococcus aureus CFU/ ml	< 1	< 1	ISO 6888-1		
iv.	Salmonella spp, in 25 ml	Absent	Absent	ISO 6579-1		
i.	Listeria monocytogenes in 25 ml	N/A	Absent	ISO 11290-1		
ii.	Escherichia coli CFU/ml	N/A	< 1	ISO 11866-2		
N/A Not Applicable						

7 Contaminants

7.1 Pesticide residues

Lactose free milk shall comply with those maximum residue limits for pesticides established by the Codex Alimentarius Commission

7.2 Veterinary drugs residues

Lactose free milk shall comply with maximum residue limits for antibiotics and other veterinary drugs set by Codex Alimentarius Commission in CX/MRL2

7.3 Aflatoxin

When tested in accordance with ISO 14501, the level of Aflatoxin M1 shall not exceed 0.5 µg/kg

7.4 Heavy metals

The level of Lead (Pb) shall not exceed 0.02 mg/kg when tested in accordance with ISO/TS 6733

8 Packaging

Lactose free milk shall be packaged in food grade packaging material that safeguards the quality, integrity and safety of the product.

9 Labelling

9.1 General labelling requirements

In addition to requirements of EAS 38, the following information shall be provided

- a) name of the product as "lactose free milk"
- b) category of lactose free milk as "Whole Milk /full cream milk; Fat Reduced Milk/semi skimmed milk/low fat milk or Fat Free Milk /skimmed milk
- c) [declaration of lactose content]
- d) fat content

9.2 Nutritional labelling

Nutrition labelling shall be done in accordance with EAS 803

9.3 Health and nutrition claims

Health and nutrition claims may be used in accordance with EAS 804 and EAS 805.

10 Sampling

Sampling for lactose free milk shall be done in accordance with ISO 707.

Annex A

(normative)

Determination of pH variation

A.1 Apparatus

A.1.1 Incubator, adjusted at 55 °C \pm 1 °C

A.1.2 pH meter

A.2 Procedure

A.2.1 Determine the pH of 50 ml of the sample in the flask, with a glass electrode at 20 °C and note reading. Then incubate another 50 ml of the sample at 55 °C \pm 1 °C for seven days. Examine the flask each day, then shake and replace it in the incubator. If any physical alteration of the contents is observed (coagulation with, or without exudation, grittiness, flocculation, formation of bubbles or scum peptonization or proteolysis) the result of the test shall be considered positive and the sample as nonsterile.

A.2.2 If no alteration takes place during the seven days' incubation at 55 °C \pm 1 °C remove the sample from the incubator and cool to room temperature. Take a small portion of it and measure the pH in the pH meter with glass electrode at 20 °C. From this pH value subtract the initial pH value (A.2.1).

A.3 Interpretation of results

A sample which does not show any physical alteration during incubation at 55 °C \pm 1 °C for seven days and where the pH does not show a difference of more than 0.3 unit from the initial pH is considered sterile.

Annex B

(normative)

Determination of titratable acidity

B.1 Apparatus

- B.1.1 Incubator
- B.1.2 Burette; with soda-lime guard tube
- B.1.3 Porcelain dishes; white hemispherical of approximately 60 ml
- B.1.4 Stirring rods; of glass, flattened at one end

B.2 Reagents

B.2.1 Standard sodium hydroxide solution

Prepare concentrated stock solution of sodium hydroxide by dissolving equal parts of sodium hydroxide (stocks or pellets) in equal parts of water in a flask. Tightly stopper the flask with a rubber bung and allow any insoluble sodium carbonate to settle down for three to four days.

Use the clear supernatant liquid for preparing the standard 0.1 M solution. About 8 ml of stock solution is required per litre of distilled water. The solution should be accurately standardized against acidic potassium phthalate or oxalic acid.

B.2.2 Phenolphthalein indicator solution

Dissolve 1 g of phenolphthalein in 110 ml rectified spirit. Add 0.1 M sodium hydroxide solution until one drop gives a faint pink coloration.

B.2.3 Rosaniline Acetate Stock Solution

Dissolve 0.121 g of rosaniline acetate in approximately 50 ml of rectified spirit, containing 0.5 ml of facial acetic acid. Make up to 100 ml with rectified spirit.

B.2.4 Bench solution

Dilute 1 ml of stock solution to 500 ml with a mixture of rectified spirit and distilled water in equal proportions by volume.

The stock and the bench solutions shall be stored in dark brown bottles securely stoppered with rubber bungs.

B.3 Procedure

B.3.1 Acidity of fresh sample

Weigh 10.0 g of the sample into each of the two white porcelain dishes of approximately 60 ml capacity; add to both 10 ml of water and stir to disperse the sample. Prepare from one dilution a colour control by addingand stirring 2 ml dilute rosaniline acetate solution. Stir 2 ml phenolphthalein solution into the other dilution and while stirring vigorously, add as rapidly as possible sodium hydroxide solution from a 10-ml burette fitted with a soda- lime guard tube, until the colour matches the pink colour of the control. The titration shall be done in bright light.

B.3.2 Acidity after incubation

Incubate another 20 g of sample at 55 °C \pm 1 °C for five days. Examine the flask each day, then shake and replace it in the incubator. If any physical alteration of the content is observed the results of the test shall be considered positive and the sample as non-sterile.

If no alteration takes place during the five days' incubation remove the sample from the incubator and cool to room temperature. Weigh 10 g of the incubated sample and determine acidity as described in B.3.1.

B.4 Calculation

B.4.1 Acidity of fresh sample

Titratable acidity (as lactic acid) per cent by weight =

m MV .9/w

where

V is the volume in ml of the standard sodium hydroxide required for titration (see B.3.1)

- M is the molarity of the standard sodium hydroxide solution (see B.3), and
- *m* is the mass in g of the sample taken for test (see B.3.1).
- w is the weight in g of the sample taken for the test (see $\textbf{B}_2.1$)

B.4.2 Acidity after incubation

B.4.2.1 Titratable acidity (as lactic acid) percent by weight =

MV .9/w

where

- V is the volume in ml of the standard sodium hydroxide required for titration (see B.2.1),
- *M* is the molarity of the standard sodium hydroxide solution (see B.2.1),
- w is the weight in g of the sample taken for the test (see B.2.1)

B.4.2.2 Subtract the value obtained in B.4.1 from the value obtained in B.4.2 which would give increase in acidity.

B.5 Interpretation of results

A sample which does not show any physical alteration during incubation at 55 $^{\circ}$ C ± 1 $^{\circ}$ C for five days and where the acidity does not show a difference of more than 0.02 g from the initial acidity is considered sterile.

Annex C

(normative)

Determination of density in milk

C.1 General

The density is a relationship between the body mass and the volume this body occupies in the space. The density test is performed in order to be used in the detection of adulteration in the milk since, the addition of water only would cause the decrease in density, whereas the skimming (fat removal) would cause an increased density in the milk, beside supplying important information for the determination of the total dry extract.

C.2 Equipment

The following equipment shall be used:

- a) Thermolactodensimeter (TLD); and
- b) Test tube (250 mL).

C.3 Methods

The density determination is accomplished by the Thermolactodensimeter because the practicability of this method.

C.4 Procedure

C.4.1 Place the sample to be analyzed in the clean and dry test tube by taking the care of inclining the test tube and allowing the liquid to flow down the walls of the glass for avoiding the incorporation of the air which would reduce the density of the milk.

C.4.2 Immense TLD into the test tube and make it rotate slowly on its own axis.

C.4.3 Perform the reading of both density and temperature of the milk as soon as TLD stabilizes.

C.4.4 Proceed to the correction of the influence from the temperature, by using an adequate scale. The result will correspond to the corrected milk density.

