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Fortified wheat flour — Specification

ICS 67.060

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EAST AFRICAN STANDARD

Fortified wheat flour — Specification

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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.

FDEAS 767 was prepared by 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 second edition cancels and replaces the first 2012 edition (EAS 767: 2012), which has been technically revised.

Introduction

The Health Ministers of the East, Central and Southern Africa Health Community (ECSA-HC) passed a resolution in 2002 directing the Secretariat to work with the countries to fortify commonly consumed foods in the region after recognizing that there is high level of malnutrition in the region. ECSA-HC is an intergovernmental organization that fosters cooperation in health among countries in the East, Central and Southern African Region. ECSA-HC members include Kenya, Uganda, Tanzania, Malawi, Zambia, Zimbabwe, Lesotho, Swaziland, Mauritius and Seychelles.

Following initial promotion efforts, the countries identified staple foods suitable for fortification as oil, sugar, maize meal/ flour and wheat flour. These foods can be used as vehicles to deliver essential micronutrients to the populations. Based on scientific evidence and working with countries using country data, the Secretariat developed implementation focused guidelines on fortification of these foods to help countries start up programmes and scale up the existing programmes. These guidelines included fortification levels for addition of micronutrients at the factory, and levels for monitoring at commercial level.

Based on the guidelines and other available information, most of the countries in the East African Region and in the larger Africa have initiated national programmes on oil fortification with vitamin A; and wheat and maize meal/flour fortification with iron, zinc, folic acid, niacin, vitamin B-1, B-2, B-12, B-6 and vitamin A. Sugar fortification with vitamin A has also been considered as a way of supplementing other sources of the vitamin in order to prevent and reduce problems associated with the deficiency of this vitamin. Salt fortification with iodine continues to be implemented in all the countries.

With the increased trade of food commodities including these fortified foods within the region, it has become imperative to develop regional standards that over and above the other standards, stipulate minimum and maximum levels of the added nutrients, provide clauses on how to pack the fortified product and the use of health and nutrition claims. The guidelines developed through ECSA have now been incorporated into food standards to provide for specific fortified products.

It is envisaged that, the implementation of these standard within the region will help countries adopt food fortification as a strategy to prevent, alleviate or eliminate micronutrient deficiency in the region. Standards will not only promote the health of the population but will also ensure safety of food products and enhance fair trade.

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Fortified wheat flour — Specification

1 Scope

This East African Standard specifies the requirements, sampling and test methods for fortified wheat flour prepared from common wheat (*Triticum aestivum* L.), club wheat (*T. compactum* Host.) or a mixture thereof intended for human consumption.

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 2001.13, *Determination of Vitamin A (Retinol) in food — Liquid Chromatography*

AOAC 2004.05, *Total folates in cereal and cereal foods — Microbiological Assay-Trienzyme Procedure*

AOAC 2011.14, *Calcium, Copper, Iron, Magnesium, Manganese, Potassium, Phosphorus, Sodium and Zinc in fortified food products. Microwave Digestion and Inductively Coupled Plasma-Optical Emission Spectrometry*

AOAC 932.03, *Determination of Carbon dioxide (total) in self-rising flour*

AOAC 944.02, *Iron in flour. Spectrophotometric method*

AOAC 952.13, *Arsenic in food — Silver diethyldithiocarbamate*

AOAC 953.17, *Thiamine (vitamin B₁) in grain products. Fluorometric (rapid) method*

AOAC 961.15, *Vitamin B₆ (pyridoxine, pyridoxal, pyridoxamine) in food extracts. Microbiological method*

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

AOAC 975.41, *Niacin and niacinamide in cereal products. Automated method*

CODEX STAN 192, *General standard for food additives*

EAS 1, *Wheat flour — Specification*

EAS 38, *Labelling of pre-packaged foods — Specification*

EAS 39, *Code of practice for hygiene in the food and drink manufacturing industry*

EAS 44, *Milled maize products — Specification*

EAS 51, *Wheat grains — Specification*

EAS 803, *Nutrition labelling — Requirements*

EAS 804, *Claims on food — General requirements*

EAS 805, *Use of nutrition and health claims — Requirements*

EAS 900, *Cereals and Pulses - Sampling*

EAS 901, *Cereals and Pulses – Test Methods*

ISO 16649-2, *Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of beta-glucuronidase-positive Escherichia coli -- Part 2: Colony-count technique at 44 degrees C using 5-bromo-4-chloro-3-indolyl beta-D-glucuronide*

ISO 20634, *Infant formula and adult nutritionals — Determination of vitamin B₁₂ by reversed phase high performance liquid chromatography (RP-HPLC)*

ISO 21527-2, *Microbiology of food and animal feedstuffs — Horizontal method for the enumeration of yeasts and moulds — Part 2: Colony count technique in products with water activity less than or equal to 0.95*

ISO 2171, *Cereals, pulses and by-products — Determination of ash yield by incineration*

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 5498, *Agricultural food products — Determination crude fibre content — General method*

ISO 6561-1, *Fruits, vegetables and derived products — Determination of cadmium content — Part 1 — Method using graphite furnace atomic absorption spectrometry*

ISO 6561-2, *Fruits, vegetables and derived products -- Determination of cadmium content -- Part 2: Method using flame atomic absorption spectrometry*

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 6633, *Fruits, vegetables and derived products — Determination of lead content — Flameless atomic absorption spectrometric method*

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

3 Terms and definitions

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

- 3.1**
diluent
suitable, inert, edible food-grade carrier for micronutrients
- 3.2**
fortification premix
blend of fortificants and diluents formulated to provide specified and determinable amounts of micronutrients
- 3.3**
fortified wheat flour
wheat flour to which essential micronutrients have been added
- 3.4**
fortificant
compound which contains essential micronutrient intended to be added to a food

3.5

food fortification

practice of deliberately increasing the content of an essential micronutrient, i.e. vitamins and minerals (including trace elements) in a food, so as to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health

3.6

wheat flour

product prepared from common wheat grain, *Triticum aestivum* L. or club wheat, *Triticum compactum* Host, or mixtures thereof by grinding or milling process

3.7

white wheat flour

wheat flour obtained by milling wheat grains at extraction rates that leaves negligible amounts of bran

3.8

baker's flour

white wheat flour made from semi hard/hard wheat which has a medium to high protein content intended for bread making

3.9

home baking/all-purpose flour

white wheat flour obtained by milling either soft wheat grains or blends of hard and soft wheat grains used for making wide range of baked products

3.10

biscuit flour

white wheat flour obtained by milling soft wheat or a blend of hard and soft wheat with a high percentage of soft wheat for biscuit manufacture

3.11

cracker flour

white wheat flour obtained by milling medium protein wheat with no improvers

3.12

self-raising flour

white wheat flour obtained by milling soft or a blend of soft and hard wheat to which raising agents are added

3.13

standard flour

wheat flour obtained by milling wheat grains at a higher extraction than home baking flour

3.14

wholemeal flour

wheat flour obtained by milling the entire wheat grain to fine particle size without any separation

3.15

atta flour

wheat flour of high extraction rate or white wheat flour to which pollard and or bran are blended

3.16

food grade packaging material

material which will safeguard the hygienic, nutritional, technological, and organoleptic qualities of the product

3.17

foreign matter

organic or inorganic material other than wheat flour

3.18**patent flour**

White wheat flour obtained by milling wheat grains at a lower extraction rate

4 Requirements**4.1 Raw materials**

Fortified wheat flour shall be prepared from wheat flour complying with EAS 1 or wheat grains complying with EAS 51.

4.2 General requirements

4.2.1 Edible salt, if used, shall comply with EAS 35.

4.2.2 Fortified wheat flour shall:

- a) have the characteristic colour of the wheat flour;
- b) be free from any objectionable flavours and odours;
- c) be free from insects, worms, fungal infestation, rodent contaminations and foreign matter; and
- d) not contain flour from other cereals. However, the addition of malted barley flour not exceeding 1 % is permissible in the case of baker's flour.

4.3 Specific requirements

Fortified wheat flour shall comply with the requirements given in Table 1 when tested in accordance with the test methods specified therein.

Table 1 — Specific requirements for fortified wheat flour

S/N	Characteristic	Requirements									Test method
		Patent wheat flour	Baker's flour	Home baking flour	Biscuit flour	Cracker flour	Self-raising flour	Standard flour	Atta flour	Whole meal flour	
i.	Moisture content, max.%, m/m	14	14	14	14	14	14	14	14	14	EAS 901, Clause 5
ii.	Crude fibre content, max.%, m/m	1.0	1.0	1.0	1.0	1.0	1.0	1.5	2.0	2.0	ISO 5498
iii.	Total ash content, max.%, m/m	0.7	0.8	0.8	0.8	0.8	3.0	1.10	2.0	2.0	ISO 2171
iv.	Residue on sieving through 180-micron sieve, max %	0.5	0.8	0.8	0.8	0.8	0.80	30.0	55.0	30.0	EAS 901, Clause 4
v.	Crude protein content, min. % m/m	8.0	9.0	8.0	8.0	8.0	8.0	9.0	8.0	8.0	EAS 901, Clause 6

4.4 Self-raising flour

In addition to the specific requirements in Table 1, self-raising fortified wheat flour shall contain the following:

- sodium bicarbonate in sufficient amounts to provide not less than 0.4 % of available carbon dioxide when tested in accordance with AOAC 932.03; and
- acid ingredients singly or in combination including sodium acid pyrophosphate, mono acid calcium phosphate and sodium aluminium phosphate.

5 Fortification requirements

5.1 Levels of micronutrients

The fortified wheat flour shall comply with the levels of micronutrients provided in Table 2 when tested in accordance with test methods specified therein.

Table 2 — Requirements for levels of micronutrients in fortified wheat flour

Nutrient	Fortificant	Limits mg/kg		Test method
		Min.	Max.	
Vitamin A ^a	Vitamin A (Retinyl) palmitate, spray-dried or equivalent, 75 000 µg RE/g ^b (7.5 % retinol), min.	0.5	1.4	AOAC 2001.13
Vitamin B ₁ ^a	Thiamin Mononitrate, 81 %, min.	4.6	NA ^c	AOAC 953.17
Vitamin B ₂ ^a	Riboflavin, 100 %, min.	3.3	NA	AOAC 970.65
Niacin ^a	Niacinamide, 99 %, min.	30	NA	AOAC 975.41
Vitamin B ₆ ^a	Pyridoxine hydrochloride, 82 %, min.	3	NA	AOAC 961.15
Folate	Folic acid, 90.5 %, min.	1.1	3.2	AOAC 2004.05
Vitamin B ₁₂	Vitamin B ₁₂ (Water soluble), 0.1 %, min.	0.01	NA	ISO 20634
Zinc	Zinc oxide, 80 %, min.	40	80	AOAC 2011.14
Total iron	Total iron	20	NA	AOAC 944.02
^a The addition of these micronutrients is optional in Tanzania. ^b 1µg RE = 3.33 IU, RE = Retinol equivalent. ^c NA-Not Applicable. The maximum limits for these nutrients are not necessary because the upper tolerance limits of these nutrients are very high. NOTE 1 Any other fortificants listed by either British Pharmacopoeia (BP); Food Chemical Codex (FCC); Merck Index (MI); United States National Formulary (NF); European Pharmacopoeia (Ph Eur); United States Pharmacopoeia (USP); or FAO WHO Codex Alimentarius Commission may be used. NOTE 2 Only NaFeEDTA, 12.5 % Fe, min or Ferrous fumarate, 32 %, min shall be used as a source of iron so as to provide iron at 20-40 mg/kg and 30-50 mg/kg respectively for wheat flour fortification.				

5.2 Fortificants and fortification premixes

The fortificants and fortification premixes may be formulated in accordance with Annex A.

6 Food additives

6.1 Fortified wheat flour may contain food additives in accordance with CODEX STAN 192.

6.2 Azodicarbonamide (ADA) and potassium bromate shall not be used.

7 Hygiene

7.1 Fortified wheat flour shall be produced, prepared and handled in accordance with EAS 39.

7.2 The product shall comply with microbiological limits given in Table 3 when tested in accordance with the test methods specified therein.

Table 3 — Microbiological limits for fortified wheat flour

S/N	Micro-organism	Maximum limit	Test method
i.	Total aerobic count, cfu/g	10^5	ISO 4833-1
ii.	<i>Escherichia coli</i> per g	$<1 \times 10^2$	ISO 16649-2
iii.	<i>Salmonella spp</i> in 25 g	Absent	ISO 6579-1
iv.	Yeast and moulds, cfu/g	10^4	ISO 21527-2
v.	<i>Staphylococcus aureus</i> , cfu/ g	10^2	ISO 6888-1

8 Contaminants

8.1 Heavy metals

Fortified wheat flour shall comply with maximum limits for heavy metals as given in Table 4 when tested in accordance with the test methods specified therein.

Table 4 — Heavy metals limits in fortified wheat flour

S/N	Heavy metal	Limit mg/kg	Test method
i.	Arsenic (As)	0.1	AOAC 952.13
ii.	Lead (Pb)	0.2	ISO 6633
iii.	Cadmium (Cd)	0.1	ISO 6561-1 ISO 6561-2

8.2 Pesticide residues

Fortified wheat flour shall comply with the maximum pesticide residue limits established by the Codex Alimentarius Commission for this commodity.

NOTE Where the use of certain pesticides is prohibited by some Partner States, then it should be notified to all Partner States accordingly.

8.3 Mycotoxins

Fortified wheat flour shall comply with the mycotoxin limits as given in Table 5 when tested in accordance with the test methods specified therein.

Table 5 — Mycotoxins limits in fortified wheat flour

S/N	Mycotoxin	Maximum limit µg/kg	Test method EAS 901
i.	Total aflatoxins	10	Clause 9
ii.	Aflatoxin B ₁	5	Clause 10
iii.	Fumonisin	2 000	Clause 11 Clause 12

9 Weights and measures

Fortified wheat flour shall be packaged in accordance with the weights and measures regulations of the destination country.

NOTE EAC Partner States are signatory to the International Labour Organizations (ILO) Convention for maximum package weight of 50 kg where human loading and offloading is involved.

10 Packaging

10.1 Fortified wheat flour shall be packaged in food grade packaging materials.

10.2 When the product is packaged in sacks, they shall be clean, sturdy and strongly sewn or sealed.

11 Labelling

11.1 General labelling

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

- product name as “Fortified wheat flour”;
- type of wheat flour;
- name, address and physical location of the manufacturer/ packer/importer;
- lot or batch number in code or in clear format;
- brand name or registered trade mark, if any;
- net weight, in metric units;
- the declaration “Human Food”;
- storage instruction as “Store in a cool dry place away from any contaminants”;
- date of manufacture;
- best before date;
- instructions on disposal of used package; and
- country of origin.

NOTE Each product unit may also be marked with the national food fortification Logo, where the industry qualifies to use the mark.

11.2 Nutrition labelling

The names and the amount of the nutrients added in the fortified wheat flour shall be declared on the label in accordance with EAS 803.

11.3 Nutrition and health claims

Where permitted by national legislation, fortified wheat flour may have claims on the importance of the added nutrients in nutrition and health. Such claims when declared shall be in compliance with EAS 804 and EAS 805.

12 Sampling

Sampling shall be done in accordance with EAS 900.

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Annex A (informative)

Fortification premix

A.1 Fortificants

Fortificants for use shall be stable compounds complying with the specification of any of the following documents;

- a) British Pharmacopoeia (BP);
- b) Food Chemical Codex (FCC);
- c) Merck Index (MI);
- d) United States National Formulary (NF);
- e) European Pharmacopoeia (Ph Eur);
- f) United States Pharmacopoeia (USP); and
- g) FAO/WHO Codex Alimentarius Commission (CAC)

A.2 Fortification premix

The fortificants may be mixed with diluents or carrier as appropriate to form a fortification premix. Diluents or carriers shall comply with USP, BP, Ph. Eur, NF, MI, FAO/WHO CAC or FCC.

The fortification premix shall be made in such a way that at a given rate of addition to the product, the product shall comply with the requirements in Table 2. The fortification premix may be formulated to comply with the provisions given in Table A.1 or Table A.2 when Fumarate or NaFeEDTA is used respectively.

Where the fortification premix is made in accordance with Table A.1 and Table A.2, the addition rate shall be 500 g of fortification premix per metric tonne of wheat flour.

The fortification premix shall be labelled with the addition rate (that is the amount of fortification premix to be added to the wheat flour) in grams of fortification premix per metric tonne of wheat flour and dilution factor.

NOTE This fortification premix formulation Table A.1 and A.2 is designed with minimum nutrient composition and does not take into consideration factory overages in the preparations of the fortification premix.

Table A.1 — Formulation of fortification mix for addition of vitamins and minerals to wheat flour if using ferrous fumarate as source of iron

Nutrient	Fortificant	Amount of micronutrient to be added to wheat flour, mg/kg	Amount of fortificant to be added to wheat flour, mg/kg	Amount of fortificant in fortification premix, g/kg	Amount of nutrient in fortification premix, g/kg
Vitamin A	Vitamin A (Retinyl) palmitate, spray dried or equivalent, 75 000 µg RE/g ^a (7.5 % retinol) retinol, min.	1	13.3	26.6	2
Vitamin B ₁	Thiamin Mononitrate, activity level, 81%, min.	9	11.1	22.2	18
Vitamin B ₂	Riboflavin, activity level, 100 %, min.	6	6.0	12.0	12
Vitamin B ₃ (Niacin)	Niacinamide, activity level, 99 %, min.	50	50.5	101.0	100
Vitamin B ₆	Pyridoxine, activity level, 82 %, min.	6	7.3	14.6	12
Vitamin B ₉ (Folate)	Folic acid, activity level, 90.5 %, min.	2	2.2	4.4	4
Vitamin B ₁₂	Vitamin B12 (Water soluble form), activity level, 0.1 %), min.	0.02	20.0	40.0	0.04
Iron	Ferrous fumarate, activity level, 32 %, Fe, min.	40	125.0	250.0	80
Zinc	Zinc oxide, activity level, 80 %, min.	30	37.5	75	60
Filling material (at least 25 %)			227.1	454.2	—
TOTAL			500	1 000.0	—

Table A.2 — Formulation of fortification mix for addition of vitamins and minerals to wheat flour if using NaFeEDTA as source of Iron

Nutrient	Fortificant	Amount of micronutrient to be added to wheat flour, mg/kg	Amount of fortificant to be added to wheat flour, mg/kg	Amount of fortificant in fortification premix, g/kg	Amount of nutrient in fortification premix, g/kg
Vitamin A	Vitamin A (Retinyl) palmitate, spraydried or equivalent, 75 000 µg RE/g ^a (7.5 % retinol) retinol, min.	1	13.3	26.6	2
Vitamin B ₁	Thiamin Mononitrate, activity level, 81 %, min.	9	11.1	22.2	18
Vitamin B ₂	Riboflavin, activity level, 100 %, min.	6	6.0	12.0	12
Vitamin B ₃ (Niacin)	Niacinamide, activity level, 99 %, min.	50	50.5	101.0	100
Vitamin B ₆	Pyridoxine hydrochloride, activity level, 82 %, min.	6	7.3	14.6	12
Vitamin B ₉ (Folate)	Folic acid, activity level, 90.5 %, min.	2	2.2	4.4	4
Vitamin B ₁₂	Vitamin B ₁₂ , (Water soluble form), activity level, 0.1 %, min.	0.02	20.0	40.0	0.04
Iron	NaFeEDTA, activity level, 12.5 % Fe, min.	30	240	480	60
Zinc	Zinc oxide, activity level, 80 %, min.	30	37.5	75	60
Diluent (Filling material, at least 25 %)			112.1	224.2	-
TOTAL			500	1 000.0	-

A.3 Stability of fortificants and fortification premixes

The supplier of the fortification premix shall provide the stability data for the fortificants and fortification premixes.

The fortificants and fortification premixes shall have storage stability such that no more than 20 % of their original activity will be lost when stored for 21 days at 45 °C in a well closed container at a level of 2.5 g/kg in wheat flour having the moisture content in the range of 13.5 % - 14 % for testing stability.

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