DRAFT EAST AFRICAN STANDARD

Fortified wheat flour — Specification

EAST AFRICAN COMMUNITY

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Foreword

Development of the Draft East African Standard 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 which are encountered when goods and services are exchanged within the Community will be removed.

In order to meet the above objectives, the EAC Partner States have enacted an Draft East African Standardization, Quality Assurance, Metrology and Testing Act, 2006 (EAC SQMT Act, 2006) to make provisions for ensuring standardization, quality assurance, metrology and testing of products produced or originating in a third country and traded in the Community in order to facilitate industrial development and trade as well as helping to protect the health and safety of society and the environment in the Community.

Draft East African Standards are formulated in accordance with the procedures established by the Draft East African Standards Committee. The Draft East African Standards Committee is established under the provisions of Article 4 of the EAC SQMT Act, 2006. The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the private sectors and consumer organizations. Draft 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 procedures of the Community.

Article 15(1) of the EAC SQMT Act, 2006 provides that “Within six months of the declaration of an Draft East African Standard, the Partner States shall adopt, without deviation from the approved text of the standard, the Draft East African Standard as a national standard and withdraw any existing national standard with similar scope and purpose”.

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

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Introduction

The Health Ministers of the East, Central and Southern Africa (ECSA) Health Community passed a resolution in 2002 directing the Secretariat to work with the countries to fortify commonly consumed foods in the region after recognizing that the high levels of malnutrition in the region. ECSA-HC is an inter-governmental organization that fosters cooperation in health among countries in the East, Central and Southern African Region. It has 10 active member states namely Kenya, Uganda, Tanzania, Malawi, Zambia, Zimbabwe, Lesotho, Swaziland, Mauritius and Seychelles. The mandate of the organization is to promote relevance and efficiency in health in the region.

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 programs and scale up the existing programs. 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 programs on oil fortification with vitamin A; and wheat and maize meal/flour fortification with iron, zinc, folic acid, niacin, vitamin B-1, B-2 and 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 adoption of these standards and their utilization 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.

This standard was developed with support from the East, Central and Southern African Health community (ECSA-HC) Secretariat. This was possible through a grant by the A2Z Project of the United States Agency for International Development (USAID). The financial and technical support was used in the process of formulation of fortification levels, development of the draft standards and mobilization of stakeholders to review the standard in national and regional fora. This support is hereby acknowledged.

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Fortified wheat flour — Specification

1 Scope

This Draft East African Standard specifies the requirements and methods of sampling and test for fortified wheat flour prepared from common wheat. *Triticum aestivum L.* or club wheat, *Triticum compactum Host*, or mixtures thereof intended for human consumption. It does not apply to wheat flour obtained from *Triticum durum.*

2 Normative references

The following normative documents contain provisions which, through reference in this text constitute provisions of this standard

EAS 1, *Wheat flour—Specification*

EAS 38, *Labelling of prepackaged foods — Specification*

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

EAS 51, *Wheat grains — Specification*

EAS 35, *Fortified food grade salt — Specification*

EAS 103, *General standard for food additives*

CAC/GL 1, *General guidelines on claims*

CAC/GL 2, *Guidelines on nutrition labelling*

CAC/GL 23, *Guidelines for use of nutrition and health claims*

CODEXSTAN 193, *General standard for contaminants and toxins in food and feed*

ISO 711, *Cereals and cereal products — Determination of moisture content (Basic reference method)*

ISO 712, *Cereals and cereal products — Determination of moisture content — Reference method*

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

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

ISO 6579, *Microbiology of food and animal feeding stuffs — Horizontal method for the detection of Salmonella spp*.

ISO 7251, *Microbiology of food and animal feeding stuffs — Horizontal method for the detection and enumeration of presumptive Escherichia coli — Most probable number technique*

ISO 13690, *Cereals, pulses and milled products — Sampling of static batches*

ISO 16050, *Foodstuffs — Determination of aflatoxin B1, and the total content of aflatoxins B1, B2, G1 and G2 in cereals, nuts and derived products — High-performance liquid chromatographic method*

ISO 20483, *Cereals and pulses – Determination of the nitrogen content and calculation of the crude protein content —– Kjeldahl method*

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*

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3 Terms and definitions

For the purposes of this standard the terms and definitions in EAS 1 and the following shall apply:

3.1
diluent
suitable, inert, edible food-grade carrier for micronutrients

3.2
premix
blend of fortificants and diluents formulated to provide specified and determinable amounts of micronutrients

3.3
fortified wheat flour
wheat flour to which nutrients have been added in accordance with this standard

3.4
fortificant
compound which contains the specified micronutrient intended to be added to a food

3.5
food fortification
practice of deliberately adding essential micronutrients in a food so as to improve the nutritional quality of the food and to provide a public health benefit with minimal risk to health

3.6
food grade container
container which will safeguard the hygienic, nutritional, technological, and organoleptic qualities of the product

4 Requirements

4.1 General requirements

4.1.1 The wheat grain from which the flour is obtained shall comply with EAS 51.

4.1.2 Edible salt, if used, shall conform to EAS 35.

4.1.3 Fortified wheat flour shall have the characteristic colour and shall

a) be free from any objectionable flavours and odours;

b) be free from insects, worms, fungal infestation, rodent contaminations and foreign matter;

c) 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.

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4.2 Specific requirements

All types of fortified wheat flour shall conform to the compositional requirements given in Table 1.

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

a) Sodium bicarbonate in sufficient amounts to provide not less than 0.4 % of available carbon dioxide;

b) Acid ingredients singly or in combination including sodium acid pyrophosphate, mono acid calcium phosphate and sodium aluminium phosphate; and

c) Edible salt may be added in self raising flour.

Table 1 — Specific requirements

Parameter	Baker's flour	Home baking flour	Biscuit flour	Cracker flour	Self-raising flour	Standard flour	Atta flour	Whole-meal flour	Method of test
Moisture content, %, by mass, max.	14	14	14	14	14	14	14	14	ISO 6540
Crude fibre content, % by mass, max.	1.0	1.0	1.0	1.0	1.0	1.5	2.0	2.0	ISO 5498
Total ash content, % by mass, max	0.8	0.8	0.8	0.8	3.0	1.10	2.0	2.0	ISO 2171
Residue on sieving through 180 micron-sieve, % by mass, max.	0.8	0.8	0.8	0.8	0.8	30.0	55.0	30.0	AOAC 965.22
Crude protein content, % by mass, min.	11.0	8.0	8.0	8.0	8.0	11.0	8.0	8.0	ISO 1871

5 Fortification requirements

5.1 Levels of micronutrients

The wheat flour shall be fortified with all the micronutrients indicated using the fortificants shown, in such a way that the product conforms to the limits set in Table 2.

Factories should aim at fortifying the products at the recommended factory level to ensure the product conforms to the regulatory levels throughout the distribution chain.

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Table 2 — Requirements for levels of micronutrients in fortified wheat flour[1]

Nutrient	Fortificant compound	Recommended factory level, mg/kg	Regulatory levels, mg/kg	
			Min	Max
Vitamin A[1]	Vitamin A (Retinyl) palmitate , spray- dried or equivalent, 0.075 % retinol, min.	1.0±0.4	0.5	1.4
Vitamin B_1[1]	Thiamin Mononitrate, activity level, 81 %, min.	9.8± 4.4	4.6	NA[2]
Vitamin B_2[1]	Riboflavin, activity level, 100 %, min.	6.6±3	3.3	NA[2]
Niacin[1]	Niacinamide, activity level, 99 %, min.	60±30	30	NA[2]
Vitamin B_6[1]	Pyridoxine, activity level, 82 %, min.	6.5±3.5	3	NA[2]
Folate	Folic acid, activity level, 100 %, min.	2.3±1	1.1	3.2
Vitamin B_{12}	Vitamin B_{12} (Water soluble), activity level, 0.1 %, min.	0.02±0.009	0.01	NA[2]
Zinc	Zinc oxide, activity level, 80 %, min.	60±20	40	80
Total iron	Total iron	30±10	20	NA[2]
Added Iron	NaFeEDTA [1,3] activity level, 13 % Fe, min.	30±10	20	40
	Ferrous fumarate[3] activity level, 32 %, min	40±10	30	50

[1]The addition of these micronutrients is optional in Tanzania.

[2]NA-Not applicable. The maximum limits for these nutrients are not necessary because the upper tolerance limits of these nutrients are very high.

[3] The use of one of these would be considered.

5.2 Fortificants

Fortificant for use shall be stable compounds conforming to specifications in any of the following documents:

- British Pharmacopoeia (BP),
- Food Chemical Codex (FCC),
- Merck Index (MI),
- United States National Formulary (NF),

[1] NaFeEDTA-Sodium iron Ethylenediamine tetraacetic acid

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- European Pharmacopoeia (Ph. Eur),
- United States Pharmacopoeia (USP);
- FAO/WHO Codex Alimentarius Commission (CAC).

NOTE For the addition of iron, premix producers may either use NaFeEDTA at the levels provided, which should be tried first to test for compatibility with the flour and if low levels are needed, or the producer may use ferrous fumarate.

5.3 Premix

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

The premix shall be made in such a way that at a given rate of addition to the product, the product shall conform to the requirements in Table 2. The premix may be formulated to conform to the provisions given in Table 3 or Table 4 when Fumarate or NaFeEDTA is used respectively.

Where the premix is made in accordance with Table 3, the addition rate shall be 500 g of premix per metric tonne of wheat flour. Where the premix is made in accordance with Table 4, the addition rate shall be 600 g of premix per metric tonne of wheat flour.

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

NOTE This premix formulation in Table 3 and Table 4 is designed with minimum nutrient composition and does not take into consideration factory overages in the preparations of the premix.

Table 3 — Formulation of fortification mix for addition of vitamins and minerals to wheat flour if using ferrous fumarate as source of iron

Nutrient	**Fortificant compound**	**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 premix,** g/kg premix	**Amount of nutrient in premix,** g/kg premix
Vitamin A	Vitamin A (Retinyl) palmitate , spray-dried or equivalent, 0.075 % retinol, min.	1	13.3	26.7	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, 100 %, min	2	2.2	4.4	4
Vitamin B_{12}	Vitamin B_{12} (Water soluble form), activity level, 0.1 %)	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	93.8	75
	Filling material (at least 25%)		68.2	317.5	
		TOTAL	341.2	1000	

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Table 4 — Formulation of fortification mix for addition of vitamins and minerals to wheat flour if using NaFeEDTA as source of Iron

Nutrient	Fortificant compound	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 premix, g/kg premix	Amount of nutrient in premix, g/kg premix
Vitamin A	Vitamin A (Retinyl) palmitate , spray- dried or equivalent, 0.075 % retinol, min.	1	13.3	26.7	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, 100 %, 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, 13 % Fe, min.	30	230.8	461.5	60
Zinc	Zinc oxide, activity level, 80 %, min.	30	37.5	93.8	75
	Diluent (Filling material, at least 25 %)		94.7	53.1	
		TOTAL	**473.4**	**1000.0**	

5.4 Stability of fortificants and premixes

The Vitamin fortificants and premixes shall have storage stability such that no more than 20 % of its original activity will be lost when stored for 21 days at 45 °C in a well closed container at a level 2.5g per kg in wheat flour having moisture content in the range of 13.5 % - 14.5 %.

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

6 Food additives

Fortified wheat flour may contain only the permitted food additives in the Codex Stan 192. The use of Azordicarbonamide (ADA) and potassium bromate is not allowed.

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7 Hygiene

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

7.2 The product shall conform to microbiological limits in Table 5.

Table 5 — Microbiological limits

S/No.	Micro-organism	Maximum limit	Methods of test
i)	Total aerobic count per g	10^5	ISO 4832
ii)	*E. Coli* per 1 g	Absent	ISO 16649-1
iii)	*Salmonella* per 25 g	Absent	ISO 6579
iv)	Yeast and Moulds cfu/g	10^4	ISO 7954
v)	*S.aureus* per 25 g	10^2	ISO 6888-1

8 Contaminants

8.1 Heavy metals

Wheat flour shall conform to those maximum limits for heavy metals established by the Codex Alimentarius Commission as specified in Table 6.

Table 6 — Heavy metals

S/N	Heavy metal	Limits (mg/kg)	Test methods
i)	Arsenic (As)	0.1	ISO 27085
ii)	Lead (Pb)	0.2	ISO 6633
iii)	Cadmium (cd)	0.1	ISO 6561-1 or ISO 6561-2

8.2 Pesticide residues

Wheat flour shall conform to those maximum pesticide residue limits established by the Codex Alimentarius Commission for this commodity.

8.3 Mycotoxins

Wheat flour shall conform to the maximum mycotoxin limits established by the Codex Alimentarius Commission as specified in Table 7.

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Table 7 — Mycotoxins

S/N	Mycotoxins	Limits	Test methods
i)	Total aflatoxins, µg/kg, max	10	ISO 16050.
ii)	Aflatoxins B1, µg/kg, max	5	
iii)	Fumonisins, µg/kg, max	2000	AOAC 2001.04

9 Weights and measures

The fill and the weight of the product shall conform to weights and measures regulations of the importing partner states.

10 Packaging

Fortified wheat flour Wheat flour shall be packaged in food grade containers. When the product is packaged in sacks, these must be clean, sturdy and strongly sewn or sealed.

11 Labelling

11.1 General labelling

Labelling shall be done in accordance with EAS 38. At the minimum, the following information shall be displayed:

a) product name as “fortified wheat flour”

b) name, address and physical location of the manufacturer/ packer/importer;

c) lot/batch/code number;

d) net weight, in kg;

e) the declaration “Food for Human Consumption’’;

f) storage instruction as “Store in a cool dry place away from any contaminants’’;

g) date of manufacture;

h) expiry date;

i) instructions on disposal of used package; and

j) country of origin;

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

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The names and the amount of the nutrients added in the fortified wheat flour shall be declared on the label in accordance with CAC/GL 2.

11.3 Nutrition and health claims

Fortified wheat flour may have claims on the importance of the added nutrients in nutrition and health. Such claims when declared shall be consistent with CAC/GL 1 and CAC/GL 23.

12 Methods of sampling

Sampling shall be done in accordance with ISO 24333.

13 Methods of test

Testing for micronutrients may be conducted using any ECSA[2] or any other internationally recognized test methods

[2] Manual of methods for determining micronutrients in fortified foods. www.a2zproject.org/-a2zorg/pdf/Manual_Foods.pdf

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Bibliography

[1] Codex standard 152-1985, Codex standard for wheat flour

[2] ECSA-HC Guidelines of fortification levels for staples

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