DRAFT EAST AFRICAN STANDARD

Fortified milled maize (corn) products — Specification
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Foreword

Development of the 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 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.

East African Standards are formulated in accordance with the procedures established by the East African Standards Committee. The 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 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 East African Standard, the Partner States shall adopt, without deviation from the approved text of the standard, the East African Standard as a national standard and withdraw any existing national standard with similar scope and purpose”.

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.

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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, B6 and B-12 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.
Fortified milled maize (corn) products — Specification

1 Scope

This draft East African standard specifies the requirements and methods of sampling and testing for fortified milled maize (corn) products namely: maize meal and maize flour from the grains of common maize (Zea mays L.) intended for human consumption.

2 Normative references

The following normative documents contain provisions which, through reference in this text constitute provisions of this East African Standard;

EAS 2, Maize (grains) — Specification
EAS 38, Labelling of prepackaged foods — Specification
EAS 39, Code of practice for hygiene in the food and drink manufacturing industry
EAS 44, Milled whole maize-meal and maize products — Specification
EAS 103, Schedule for permitted food additives
CAC/GL 1, Codex Alimentarius guidelines for claims.
CAC/GL 2, Codex Alimentarius nutrition labelling for claims
EAS 23, Guidelines for use of nutrition and health claims
CODEXSTAN 193, Codex general Standards 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 4833, Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of microorganisms -- Colony-count technique at 30 degrees C
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 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
ISO 6888-2, Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) — Part 2: Technique using rabbit plasma fibrinogen agar medium
ISO 6888-3, Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) — Part 3: Detection and MPN technique for low numbers
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 7305, Milled cereal products – Determination of fat acidity
ISO 7954, Microbiology — General guidance for enumeration of yeasts and moulds — Colony count technique at 25 °C.
ISO 11085, Cereals, cereals-based products and animal feeding stuffs -- Determination of crude fat and total fat content by the Randall extraction method
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

3 Terms and definitions

For the purposes of this standard the definitions in EAS 44 and the following definitions shall apply.

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

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

3.3 fortified milled maize products
maize meal, maize flour or sifted maize meal to which micronutrients have been added in accordance with this standard

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

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

4 Quality requirements

4.1 Raw materials

Fortified milled maize products shall be produced from shelled maize conforming to the requirements of EAS 2.

4.2 General quality requirements

Fortified milled maize products shall be:

a) of natural colour conforming to the colour of maize from which it was prepared.

b) practically free from foreign matter such as insects, fungi and dirt.

c) free from fermented musty or other objectionable colours.

d) free from rancidity and foreign odours.
e) wholesome and fit for human consumption in all aspects.

### 4.3 Specific requirements

Fortified milled maize products shall conform to the requirements given in Table 1.

#### Table 1 — Specific requirements for fortified milled maize products

<table>
<thead>
<tr>
<th>Sl No.</th>
<th>Characteristic</th>
<th>Type of product</th>
<th>Test method</th>
</tr>
</thead>
<tbody>
<tr>
<td>i)</td>
<td>Crude fibre content, % by mass, max.</td>
<td>Sifted maize meal</td>
<td>0.7, 1.0, 3.0, 0.7</td>
</tr>
<tr>
<td>ii)</td>
<td>Crude fat a moisture free basis, % by mass, max.</td>
<td></td>
<td>2.25, 2.25, 3.1, 0.7</td>
</tr>
<tr>
<td>iii)</td>
<td>Moisture content, % by mass, max.</td>
<td></td>
<td>13, 13, 13, 13</td>
</tr>
<tr>
<td>iv)</td>
<td>Total ash, % by mass, max.</td>
<td></td>
<td>1.0, 1.0, 3.0, 1.0</td>
</tr>
<tr>
<td>v)</td>
<td>Acid insoluble ash, % by mass, max.</td>
<td></td>
<td>0.15, 0.35, 0.40, 0.15</td>
</tr>
<tr>
<td>vi)</td>
<td>Crude protein (N x 6.25) % by mass, min</td>
<td></td>
<td>7.0, 7.0, 8.0, 7.0</td>
</tr>
<tr>
<td>vii)</td>
<td>Fat acidity, mg KOH per 100g of product, on dry mass basis, max</td>
<td></td>
<td>50, 50, 50, 50</td>
</tr>
</tbody>
</table>

#### 5 Fortification requirements

### 5.1 Levels of micronutrients

The fortified milled maize products shall conform to the requirements and the levels of micronutrients provided in Table 2.

#### Table 2: Requirements for micronutrients in fortified milled maize products

<table>
<thead>
<tr>
<th>Sl No</th>
<th>Nutrient</th>
<th>Fortificant compound</th>
<th>Recommended factory level, mg/kg</th>
<th>Regulatory levels, mg/kg</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>i)</td>
<td>Vitamin A&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Vitamin A (Retinyl) palmitate</td>
<td>1±0.4</td>
<td>0.5, 1.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ii)</td>
<td>Vitamin B&lt;sub&gt;1&lt;/sub&gt;</td>
<td>Thiamin Mononitrate</td>
<td>6.5± 2.9</td>
<td>3.0, (9.4)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>iii)</td>
<td>Vitamin B&lt;sub&gt;2&lt;/sub&gt;</td>
<td>Riboflavin</td>
<td>4±1.8</td>
<td>2, (5.8) *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>iv)</td>
<td>Niacin&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Niacinamide</td>
<td>30±13.4</td>
<td>14.9, (43.4) *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>v)</td>
<td>Vitamin B&lt;sub&gt;6&lt;/sub&gt;</td>
<td>Pyridoxine</td>
<td>5±2.5</td>
<td>2, (7.5) *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vi)</td>
<td>Folate</td>
<td>Folic acid</td>
<td>1.2±0.5</td>
<td>0.6, 1.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vii)</td>
<td>Vitamin B12</td>
<td>Vitamin B12 0.1% WS</td>
<td>0.015±0.007</td>
<td>0.007, (0.022)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>viii)</td>
<td>Zinc</td>
<td>Zinc oxide</td>
<td>49±16</td>
<td>33, 65</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ix)</td>
<td>Total iron</td>
<td>Total iron</td>
<td>31±10</td>
<td>21, 41</td>
<td></td>
<td></td>
</tr>
<tr>
<td>x)</td>
<td>Added Iron</td>
<td>NaFeEDTA</td>
<td>20±10</td>
<td>10, 30</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>* The figures in brackets may not be necessary because the upper tolerable limit for these nutrients is very high</sup>

<sup><sup>1</sup>The addition of these micronutrients is optional in Tanzania.</sup>
5.2 Fortificants
Fortificants 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),
- European Pharmacopoeia (Ph Eur),
- United States Pharmacopoeia (USP);
- FAO/WHO Codex Alimentarius Commission (CAC),

5.3 Premix
The fortificants shall 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, 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.

NOTE 1: This premix formulation is designed with minimum nutrient composition and does not take into consideration factory overages in the preparations of the premix

Table 3 – Formulation of premix for addition of micronutrients to milled maize products

<table>
<thead>
<tr>
<th>Micronutrient</th>
<th>Fortificant compound</th>
<th>Amount of micronutrient to be added to food, mg/kg</th>
<th>Amount of fortificant to be added to food, mg/kg</th>
<th>Amount of fortificant in premix, g/kg</th>
<th>Amount of nutrient in premix, g/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>Retinyl Palmitate-250,000 IU/g (dry)</td>
<td>1.0</td>
<td>13.3</td>
<td>26.7</td>
<td>2</td>
</tr>
<tr>
<td>Vitamin B-1</td>
<td>Thiamin mononitrate</td>
<td>4.5</td>
<td>5.6</td>
<td>11.1</td>
<td>9</td>
</tr>
<tr>
<td>Vitamin B-2</td>
<td>Riboflavin</td>
<td>3.0</td>
<td>3.0</td>
<td>6.0</td>
<td>6</td>
</tr>
<tr>
<td>Vitamin B-3 (Niacin)</td>
<td>Niacinamide</td>
<td>25.0</td>
<td>25.3</td>
<td>50.5</td>
<td>50</td>
</tr>
<tr>
<td>Vitamin B-6</td>
<td>Pyridoxine</td>
<td>5.0</td>
<td>6.1</td>
<td>12.2</td>
<td>10</td>
</tr>
<tr>
<td>Vitamin B-9 (Folate)</td>
<td>Folic Acid</td>
<td>1.0</td>
<td>1.1</td>
<td>2.2</td>
<td>2</td>
</tr>
<tr>
<td>Vitamin B-12</td>
<td>Vit. B-12 0.1% WS</td>
<td>0.015</td>
<td>15.0</td>
<td>30.0</td>
<td>0.03</td>
</tr>
<tr>
<td>Iron</td>
<td>NaFeEDTA</td>
<td>20</td>
<td>153.8</td>
<td>307.7</td>
<td>37</td>
</tr>
<tr>
<td>Zinc</td>
<td>Zinc oxide</td>
<td>40</td>
<td>50.0</td>
<td>100.0</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>Filling material (at least 25%)</td>
<td></td>
<td>68.3</td>
<td>453.6</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td>341.5</td>
<td>1000.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The premix shall be labelled with the addition rate (that is the amount of premix to be added to the milled maize product) in grams of premix per metric tonne of maize product and dilution factor.
Where the premix is made in accordance with Table 3, the addition rate shall be 500 g of premix per metric tonne of maize flour.

5.4 Stability of fortificants and premixes

The 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 of 2.5g per kg in milled maize product having moisture content in the range of 13.5 % to 14.5 %.

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

6 Food additives

The product shall contain only permitted additives complying with EAS 103.

7 Hygiene

7.1 Fortified milled maize products shall be produced, prepared and handled in accordance with the provisions of appropriate sections of EAS 39.

7.2 The product shall be free from pathogenic micro-organism and shall comply with microbiological limits in Table 4.

Table 4 — Microbiological limits for milled maize products

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Micro-organism</th>
<th>Maximum limit</th>
<th>Methods of test</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i)</td>
<td>Total aerobic count, cfu, per g, max.</td>
<td>$10^5$</td>
<td>ISO 4833</td>
</tr>
<tr>
<td>(ii)</td>
<td><em>Escherichia coli</em>, MPN, per g</td>
<td>&lt; 3</td>
<td>ISO 7521</td>
</tr>
<tr>
<td>(iii)</td>
<td><em>Salmonella</em> per 25 g</td>
<td>Not detected</td>
<td>ISO 6579</td>
</tr>
<tr>
<td>(iv)</td>
<td>Yeast and Moulds, cfu/g, max.</td>
<td>$10^5$</td>
<td>ISO 7954</td>
</tr>
<tr>
<td>(v)</td>
<td><em>Staphylococcus aureus</em>, cfu, per g, max.</td>
<td>10</td>
<td>ISO 6888 -1, ISO 6888 2 or ISO 6888 -3</td>
</tr>
</tbody>
</table>

8 Contaminants

8.1 Heavy metals

Fortified milled maize products shall conform to those maximum limits for heavy metals established by the Codexstan 193.

8.2 Pesticide residues

Fortified milled maize products shall conform to those maximum residue limits established by the Codex Alimentarius Commission for this commodity.

NOTE 1: Where the use of certain pesticides is prohibited by some Partner States, then it shall be notified to all Partner States accordingly.
8.3 Mycotoxins

Fortified milled maize products shall conform to those maximum mycotoxin limits established by the Codex Alimentarius Commission for this commodity. The milled maize products shall not exceed total aflatoxin of 10 µg/kg and 5 µg/kg for aflatoxin B1 when tested in accordance with ISO 16050.

9 Packaging

9.1 Fortified milled maize products shall be packed in suitable packages which shall be clean, sound, free from insects, fungal infestation and the packing material shall be of food grade quality.

9.2 Fortified milled maize products shall be packed in containers which will safeguard the hygienic, nutritional, technological and organoleptic qualities of the products.

9.3 The containers, including packaging material, shall be made of materials which are safe and suitable for their intended use. They shall not impart any toxic substance or undesirable odour or flavour to the product.

9.4 Each package shall be securely closed and sealed.

NOTE 1: Packaging materials may be required to meet different regulations in the different destination countries.

NOTE 2: The package fill should conform to the requirements of the legal metrology of the destination country.

NOTE 3: EA Community Partner States are signatory to the (ILO) for maximum package weight for 50kg per load where human loading and offloading is involved.

10 Labelling

10.1 General labelling

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

i) The name of product as “Whole Maize Meal, Sifted Maize meal, Maize flour or Granulated Maize meal”;

ii) The word “fortified” shall be declared before the name of the product

iii) The name and address of the manufacturer/packer/importer;

iv) Brand name/registered trade mark;

v) Lot or batch number in code or in clear format;

vi) Net weight in metric units;

vii) The statement “Store in a Cool Dry Place and away from contaminants”;

viii) The statement “Food for Human Food”;

ix) Country of origin;

x) Date of manufacture;

xi) Best before date;

xii) Instructions for disposal of used package.
xiii) Each product unit may also be marked with the national food fortification Logo, where the industry qualifies to use the mark.

10.2 Nutrition labelling

The amount of micronutrients in the maize flour shall be declared on the label in accordance with CAC/GL 2.

10.3 Nutrition and health claims

Fortified milled maize products may have claims on the importance of the micronutrients in nutrition and health. Such claims when declared shall be consistent with CAC/GL 1 and CAC/GL 23.

11 Methods of sampling

Sampling shall be done in accordance with the ISO 13690 or ISO 24333.

12 Methods of Testing

Testing for micronutrients may be conducted using any ECSA methods of test.
Annex A
(normative)

Determination of acid insoluble ash

A1 Reagent
Dilute hydrochloric acid — Approximately 5 N, prepared from concentrated hydrochloric acid.

A.2 Procedure
Weigh accurately about 5 g of the product in a tared, clean and dry porcelain dish. Ignite the material in the dish with the flame of a suitable burner for about one hour. Complete the ignition by keeping in a muffle furnace at 500°C to 600°C until grey ash results. Cool in a desiccator and weigh. Repeat the process of igniting, cooling and weighing at half-hour intervals until the difference between two successive weighings is less than one milligram. Note the lowest mass.

To the ash contained in the porcelain dish add 25 mL of dilute hydrochloric acid, cover with a watch glass and heat on a water bath for 10 minutes. Allow to cool and filter the contents of the dish through Whatman filter paper No. 42 or its equivalent. Wash the filter with water until the washings are free from the acid. Return the filter and the residue to the dish. Keep it in an electric air-oven maintained at 135 ± 2 °C for about 3 hours. Ignite in a muffle furnace at about 550 °C to 600 °C for one hour. Cool the dish in a desiccator and weigh. Repeat the process of igniting in the muffle furnace, cooling and weighing at half-hour intervals until the difference between two successive weighings is less than one milligram. Note the lowest mass.

A.3 Calculation
Acid insoluble ash (on dry basis), per cent by mass

\[
\text{Acid insoluble ash} = 100 \frac{(m_2 - m)}{(m_1 - m)}
\]

where

\( m_2 \) = mass in g of the porcelain dish with the acid insoluble ash,
\( m \) = mass in g of the empty porcelain dish, and
\( m_1 \) = mass in g of the porcelain dish with the dried material taken for the determination of total ash.
Bibliography

