DRAFT EAST AFRICAN STANDARD

Fortified wheat flour — Specification

EAST AFRICAN COMMUNITY

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East African Community
P.O. Box 1096
Arusha
Tanzania
Tel: 255 27 2504253/8
Fax: 255 27 2504481/2504255
E-mail: eac@eachq.org
Web: www.eac-quality.net

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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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East African Community 
P O Box1096 
Arusha 
Tanzania 
Tel: 255 27 2504253/8 
Fax: 255-27-2504481/2504255 
E-Mail: eac@eachq.org 
Web: www.each.org

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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 intergovernmental 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.
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.), club wheat (T. compactum Host.) or a mixture thereof intended for human consumption.

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, Schedule for permitted food additives
CAC/GL 1, Codex Alimentarius guidelines for claims
CAC/GL 2, Codex Alimentarius nutrition labelling for claims
CAC/GL 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 yeasts and moulds — Colony count technique at 25 °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 6888-3, 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 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 6888-1, 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 7251, Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of presumptive Escherichia coli — Most probable number technique
ISO 7954, Microbiology — General guidance for enumeration of yeasts and moulds — Colony count technique at 25 °C.
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

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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 terms and definitions in EAS 1 and the following terms and 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 wheat flour
wheat flour to which nutrients 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

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

4 Quality requirements

4.1 Raw materials

The wheat grain from which the flour is obtained shall be of sound quality, free from sand, have characteristic odour and flavour conforming to EAS 51.

4.2 General requirements

4.2.1 Fortified wheat flour shall have the characteristic colour and shall be free from any objectionable flavours and odours.

4.2.2 The flour shall be free from insects, worms, fungal infestation, rodent contaminations and foreign matter.

4.2.3 The flour shall 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

The types of wheat flour shall comply with the compositional requirements given in Table 1

4.4 Self-raising flour

In addition to the specifications in Table 1, specific requirements for self-raising wheat flour may contain the following:
4.4.1 Edible salt conforming to EAS 35.

4.4.2 Acid ingredients

The acid ingredients shall be one or any combination of the following:

i) sodium acid pyrophosphate;

ii) mono acid calcium phosphate;

iii) sodium aluminium phosphate;

iv) sodium bicarbonate shall be in sufficient amounts to provide not less than 0.4 % of available carbon dioxide.

### Table 1 — Specific requirements

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baker’s flour</th>
<th>Home baking flour</th>
<th>Biscuit flour</th>
<th>Cracker flour</th>
<th>Self-raising flour</th>
<th>Standa rd flour</th>
<th>Atta flour</th>
<th>Whole-meal flour</th>
<th>Method of test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moisture content, max. %, m/m</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>ISO 711 or ISO 712</td>
</tr>
<tr>
<td>Crude fibre content, max.</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
<td>1.5</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
<td>ISO 5498</td>
</tr>
<tr>
<td>Total ash content, max. %, m/m</td>
<td>0.7</td>
<td>0.7</td>
<td>0.55</td>
<td>0.70</td>
<td>2.0</td>
<td>1.10</td>
<td>2.0</td>
<td>2.0</td>
<td>ISO 2171</td>
</tr>
<tr>
<td>Residue on sieving through 180 micron-sieve, max. %</td>
<td>0.8</td>
<td>0.8</td>
<td>0.5</td>
<td>0.5</td>
<td>0.8</td>
<td>30.0</td>
<td>55.0</td>
<td>30.0</td>
<td></td>
</tr>
<tr>
<td>Protein content, min. %, m/m</td>
<td>11.0</td>
<td>9.0</td>
<td>8.0</td>
<td>8.0</td>
<td>8.0</td>
<td>11.0</td>
<td>12.0</td>
<td>12.0</td>
<td>ISO 20483</td>
</tr>
</tbody>
</table>

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.
Table 2: Requirements for levels of micronutrients in fortified wheat flour

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Fortificant compound</th>
<th>Recommended factory level, mg/kg</th>
<th>Regulatory levels, mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>Vitamin A (Retinyl) palmitate</td>
<td>1.0±0.4</td>
<td>0.5</td>
</tr>
<tr>
<td>Vitamin B1</td>
<td>Thiamin Mononitrate</td>
<td>9.8± 4.4</td>
<td>4.6</td>
</tr>
<tr>
<td>Vitamin B2</td>
<td>Riboflavin</td>
<td>6.6±3</td>
<td>3.3</td>
</tr>
<tr>
<td>Niacin</td>
<td>Niacinamide</td>
<td>60±30</td>
<td>30</td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>Pyridoxine</td>
<td>6.5±3.5</td>
<td>3</td>
</tr>
<tr>
<td>Folate</td>
<td>Folic acid</td>
<td>2.3±1</td>
<td>1.1</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>Vitamin B12 (Water soluble, 0.1%)</td>
<td>0.02±0.009</td>
<td>0.01</td>
</tr>
<tr>
<td>Zinc</td>
<td>Zinc oxide</td>
<td>88±28</td>
<td>60</td>
</tr>
<tr>
<td>Total iron</td>
<td>Total iron</td>
<td>30±10</td>
<td>20</td>
</tr>
<tr>
<td>Added Iron</td>
<td>NaFeEDTA</td>
<td>30±10</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Ferrous fumarate</td>
<td>40±10</td>
<td>30</td>
</tr>
</tbody>
</table>

1 The addition of these micronutrients is optional in Tanzania.
* The maximum limits for these nutrients may not be necessary because the upper tolerance limits of these nutrients are very high.
2 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),
- 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, producer may switch to 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 FCC.

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The premix shall be made in such a way that at a given rate of addition to the product, the 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.

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 1:** 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.

**NOTE 2:** 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

<table>
<thead>
<tr>
<th>NUTRIENT</th>
<th>Fortificant compound</th>
<th>Amount of micronutrient to be added to wheat flour, mg/kg</th>
<th>Amount of fortificant to be added to wheat flour, mg/kg</th>
<th>Amount of fortificant in premix, g/kg premix</th>
<th>Amount of nutrient in premix, g/kg premix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>Retinyl Palmitate- 250,000 IU/g (dry)</td>
<td>1</td>
<td>13.3</td>
<td>26.7</td>
<td>2</td>
</tr>
<tr>
<td>Vitamin B-1</td>
<td>Thiamin mononitrate</td>
<td>9</td>
<td>11.1</td>
<td>22.2</td>
<td>18</td>
</tr>
<tr>
<td>Vitamin B-2</td>
<td>Riboflavin</td>
<td>6</td>
<td>6.0</td>
<td>12.0</td>
<td>12</td>
</tr>
<tr>
<td>Vitamin B-3 (Niacin)</td>
<td>Niacinamide</td>
<td>50</td>
<td>50.5</td>
<td>101.0</td>
<td>100</td>
</tr>
<tr>
<td>Vitamin B-6</td>
<td>Pyridoxine hydrochloride</td>
<td>6</td>
<td>7.3</td>
<td>14.6</td>
<td>12</td>
</tr>
<tr>
<td>Vitamin B-9 (Folate)</td>
<td>Folic Acid</td>
<td>2</td>
<td>2.2</td>
<td>4.4</td>
<td>4</td>
</tr>
<tr>
<td>Vitamin B-12</td>
<td>Vit. B-12 0.1% WS</td>
<td>0.02</td>
<td>20.0</td>
<td>40.0</td>
<td>0.04</td>
</tr>
<tr>
<td>Iron</td>
<td>Ferrous fumarate</td>
<td>80</td>
<td>100.0</td>
<td>200.0</td>
<td>160</td>
</tr>
<tr>
<td>Zinc</td>
<td>Zinc oxide</td>
<td>80</td>
<td>100.0</td>
<td>200.0</td>
<td>160</td>
</tr>
<tr>
<td>Filling material (at least 25%)</td>
<td></td>
<td>83.9</td>
<td>329.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>419.4</strong></td>
<td></td>
<td><strong>1000.0</strong></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Fortificant compound</th>
<th>Amount of micronutrient to be added to wheat flour, mg/kg</th>
<th>Amount of fortificant to be added to wheat flour, mg/kg</th>
<th>Amount of fortificant in premix, g/kg premix</th>
<th>Amount of nutrient in premix, g/kg premix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>Retinyl Palmitate- 250,000 IU/g (dry)</td>
<td>1</td>
<td>13.3</td>
<td>26.7</td>
<td>2</td>
</tr>
<tr>
<td>Vitamin B-1</td>
<td>Thiamin mononitrate</td>
<td>9</td>
<td>11.1</td>
<td>22.2</td>
<td>18</td>
</tr>
<tr>
<td>Vitamin B-2</td>
<td>Riboflavin</td>
<td>6</td>
<td>6.0</td>
<td>12.0</td>
<td>12</td>
</tr>
<tr>
<td>Vitamin B-3 (Niacin)</td>
<td>Niacinamide</td>
<td>50</td>
<td>50.5</td>
<td>101.0</td>
<td>100</td>
</tr>
<tr>
<td>Vitamin B-6</td>
<td>Pyridoxine hydrochloride</td>
<td>6</td>
<td>7.3</td>
<td>14.6</td>
<td>12</td>
</tr>
<tr>
<td>Vitamin B-9 (Folate)</td>
<td>Folic Acid</td>
<td>2</td>
<td>2.2</td>
<td>4.4</td>
<td>4</td>
</tr>
<tr>
<td>Vitamin B-12</td>
<td>Vitamin B-12 0.1% WS</td>
<td>0.02</td>
<td>20.0</td>
<td>40.0</td>
<td>0.04</td>
</tr>
<tr>
<td>Iron</td>
<td>NaFeEDTA</td>
<td>30</td>
<td>230.8</td>
<td>481.5</td>
<td>60</td>
</tr>
<tr>
<td>Zinc</td>
<td>Zinc oxide</td>
<td>80</td>
<td>100.0</td>
<td>200.0</td>
<td>160</td>
</tr>
<tr>
<td>Diluent (Filling material, at least 25%)</td>
<td></td>
<td>110.3</td>
<td>117.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>551.6</strong></td>
<td></td>
<td><strong>1000.0</strong></td>
<td></td>
</tr>
</tbody>
</table>
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 % to 14.5 %.

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

6 Food additives

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

7 Hygiene

7.1 Wheat flour 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 5.

Table 5 — Microbiological limits for fortified wheat flour

<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 1 g, max</td>
<td>Not detected</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>$10^4$</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, 2 and 3</td>
</tr>
</tbody>
</table>

8 Contaminants

8.1 Heavy metals

Wheat flour shall comply with those maximum limits for heavy metals established by the Codex Alimentarius Commission for this commodity.

8.2 Pesticide residues

Wheat flour shall comply with those 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 shall be notified to all Partner States accordingly.

8.3 Mycotoxins

Wheat flour shall comply with those maximum mycotoxin limits established by the Codex Alimentarius Commission for this commodity. In particular, total aflatoxin levels in wheat flour for human consumption shall not exceed 10 µg/kg (ppb) with B1 not exceeding 5 µg/kg (ppb) when tested according to ISO 16050.

9 Packaging
9.1 Fortified wheat flour 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 wheat flour 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 packages fill should conform to the requirements of the legal metrology of the destination country.

NOTE 3: EAS 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) Product name as “fortified wheat flour”

ii) Name, address and physical location of the manufacturer/packer/importer;

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

iv) Net weight, in kg;

v) The declaration “Food for Human Consumption”;

vi) Storage instruction as “Store in a cool dry place away from any contaminants”;

vii) Date of manufacture;

viii) Best before date;

ix) Instructions on disposal of used package;

x) Country of origin;

xi) 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 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.
10.3 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.

11 Methods of sampling

Sampling shall be done in accordance with the ISO 13690.

12 Methods of Testing

Testing for micronutrients may be conducted using any validated ECSA methods of test.
Bibliography
