NOTE: This is a draft proposal and it shall neither be used nor regarded as a Malawi Standard.
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FOREWORD

This draft proposal was prepared by MBS/TC 19, the Technical Committee on Bread and confectioneries, to provide requirements for fortified wheat flour.

This draft proposal is the fourth edition of MS 30, Fortified wheat flour – Specification. The review of this standard has been done incorporating the latest changes which have been made to the base document. Revision of this standard does not remove requirements for fortification that were included in the third edition at the request of the National Fortification Alliance (NFA) in order to address issues of micronutrient malnutrition prevalent in Malawi.

In preparing this draft Malawi standard, reference was made to the following standards:

Codex standard, CXS 152-1985 (Amended in 2019), Standard for wheat flour; and

Acknowledgement is made for the use of the information.

TECHNICAL COMMITTEE

This draft proposal was prepared by the MBS/TC 19, the Technical Committee on Bread and confectioneries, and the following companies, organizations and institutions were consulted:

Bakhresa Grain Milling;
Blantyre City Council;
Bread Talk;
Bvumbwe Agricultural Research Station;
International Potato Center Malawi;
Lilongwe University of Agriculture & Natural Resources;
Ministry of Health – Department of Nutrition, HIV & AIDS;
National Fortification Alliance;
Universal Industries Limited; and
University of Malawi.

NOTICE

This standard shall be reviewed every five years, or earlier when it is necessary, in order to keep abreast of progress. Comments are welcome and shall be considered when the approved is being reviewed.
DRAFT PROPOSAL

Fortified wheat flour — Specification

1 SCOPE

This draft proposal specifies the requirements and methods of sampling and analysis for fortified wheat flour prepared from common wheat (Triticum aestivum L.), club wheat (Triticum compactum Host.) or a mixture thereof intended for human consumption.

2 NORMATIVE REFERENCES

The following standards contain provisions which, through reference in this text, constitute provisions of this draft proposal. All standards are subject to revision and, since any reference to a standard is deemed to be a reference to the latest edition of the standard, parties to agreements based on this draft proposal are encouraged to take steps to ensure the use of the most recent editions of the standards indicated below. Information on currently valid national and international standards can be obtained from the Malawi Bureau of Standards:

MS 19: General standard for labelling of prepacked foods;
MS 21: Code of hygienic conditions for food processing units;
MS 55: Wheat grain – Specification;
MS 144: Agricultural food products – Determination of crude fibre content – Modified Scharrer method;
MS 145: Cereals and pulses – Methods of sampling as milled products;
MS 148: Cereal and cereal products – Determination of fat content;
MS 149: Cereals, pulses and derived products – Determination of ash;
MS 237: Food additives – General standard;
MS 302: Contaminants and toxins in foods – General standard;
MS 610: Cereals, and cereal products – Determination of moisture content (Basic reference method);
MS 624: Nutrition labelling – Guidelines;
MS 625: Nutrition claims – Guidelines;
MS 1632: General standard for the labelling of food additives when sold as such;
AOAC 965.22: Sorting corn grits. Sieving method;
ISO 1871: Agricultural food products – General directions for the determination of nitrogen by the Kjeldahl method;
ISO 4833-1: Microbiology of the food chain – Horizontal method for the enumeration of microorganisms – Part 1: Colony count at 30 °C by the pour plate technique;
ISO 6579: Microbiology of food and animal feeding stuffs – Horizontal method for the detection of Salmonella spp.;

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 7251: Microbiology of food and animal feeding stuffs – Horizontal method for the detection and enumeration of presumptive Escherichia coli – Most probable number technique;

ISO 7932/AMD 1: Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of presumptive Bacillus cereus – Colony-count technique at 30 degrees C – Amendment 1: Inclusion of optional tests;

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 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; and

ISO 21872-1: Microbiology of the food chain – Horizontal method for the determination of Vibrio spp. – Part 1: Detection of potentially enteropathogenic Vibrio parahaemolyticus, Vibrio cholerae and Vibrio vulnificus.

3 TERMS AND DEFINITIONS

For the purposes of this draft proposal, the following terms and definitions shall apply:

3.1 diluent
suitable, inert food-grade carrier for micronutrients

3.2 fortified wheat flour
product prepared from grain of common wheat (Triticum aestivum L.,) or club wheat, (Triticum compactum Host.), or mixtures thereof, by grinding or milling process in which the bran and germ are partly removed and the remainder is comminuted to a suitable degree of fineness to which nutrients have been added in accordance with this draft proposal

3.3 fortificant
prescribed compound which provides the specified micronutrient

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

4 ESSENTIAL COMPOSITION AND QUALITY FACTORS

4.1 General quality factors

4.1.1 Wheat flour and any added ingredients shall be safe and suitable for human consumption.

4.1.2 Wheat flour shall be free from abnormal flavours, odours, and living insects.

4.1.3 Wheat flour shall be free from impurities of animal origin, including dead insects when determined in accordance with MS 1787.
4.2 Essential specific composition factors

Fortified wheat flour shall conform to compositional requirements in Table 1.

Table 1 – Specific compositional requirements for fortified wheat flour

<table>
<thead>
<tr>
<th>S/N</th>
<th>Characteristic</th>
<th>Limit</th>
<th>Method of test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Fat acidity</td>
<td>70 mg/100 g flour on a dry matter basis expressed as sulphuric acid or not more than 50 mg of potassium hydroxide shall be required to neutralize the free fatty acids in 100 g flour on dry basis</td>
<td>MS 148</td>
</tr>
<tr>
<td>2</td>
<td>Protein (5.7)</td>
<td>7.0 % on a dry basis, min.</td>
<td>ISO 1871</td>
</tr>
<tr>
<td>3</td>
<td>Particle size(Granularity)</td>
<td>98 % of flour shall pass through a 212 micron (No. 70 sieve)</td>
<td>AOAC 965.22</td>
</tr>
<tr>
<td>4</td>
<td>Moisture content</td>
<td>15.5 % m/m, max.</td>
<td>MS 610</td>
</tr>
</tbody>
</table>

4.3 Optional ingredients

The following ingredients may be added to wheat flour in amounts necessary for technological purposes:

4.3.1 Malted products with enzymatic activity made from wheat, rye or barley, conforming to relevant Malawi standards;

4.3.2 Vital wheat gluten; and

4.3.3 Soybean flour or legume flour, conforming to relevant Malawi standards.

4.4 Microbiological limits

Fortified wheat flour shall be free from pathogenic micro-organisms and shall conform to the microbiological limits in Table 2.

Table 2 – Microbiological limits for fortified wheat flour

<table>
<thead>
<tr>
<th>S/N</th>
<th>Micro-organism</th>
<th>Limit</th>
<th>Method of test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Total plate count, cfu/g, max.</td>
<td>$10^3$</td>
<td>ISO 4833-1</td>
</tr>
<tr>
<td>2</td>
<td><em>Staphylococcus aureus</em>, cfu/g max</td>
<td>$10^2$</td>
<td>ISO 6888-1</td>
</tr>
<tr>
<td>3</td>
<td><em>Escherichia coli</em>, cfu/g, max.</td>
<td>Absent</td>
<td>ISO 7251</td>
</tr>
<tr>
<td>4</td>
<td>Salmonella, cfu/25 g, max.</td>
<td>Absent</td>
<td>ISO 6579</td>
</tr>
<tr>
<td>5</td>
<td>Yeast and mould, cfu/g, max.</td>
<td>$10^3$</td>
<td>ISO 21527-2</td>
</tr>
<tr>
<td>6</td>
<td>Coliforms, cfu/100 g, max.</td>
<td>absent</td>
<td>ISO 16649-2</td>
</tr>
<tr>
<td>7</td>
<td><em>Bacillus cereus</em>, cfu/25g, max.</td>
<td>Absent</td>
<td>ISO 7932/AMD 1</td>
</tr>
<tr>
<td>8</td>
<td><em>Vibrio cholerae</em></td>
<td>Absent</td>
<td>ISO 21872-1</td>
</tr>
</tbody>
</table>

5 FOOD FORTIFICATION

5.1 Required content of vitamins and minerals in fortified wheat flour

Fortified wheat flour shall contain vitamins and minerals at the levels specified in Table 3. These levels shall be applied during production of the fortified wheat flour and for imported wheat flour.
Table 3 — Fortification requirements at production and during importation

<table>
<thead>
<tr>
<th>S/N</th>
<th>Nutrient</th>
<th>Fortification compound</th>
<th>Factory addition level (mg/kg)</th>
<th>Tolerable range at factory or site of import (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Minimum</td>
<td>Average</td>
</tr>
<tr>
<td>1</td>
<td>Folate</td>
<td>Folic acid</td>
<td>2.0</td>
<td>1.3</td>
</tr>
<tr>
<td>2</td>
<td>Iron</td>
<td>Sodium iron EDTA</td>
<td>30</td>
<td>27</td>
</tr>
<tr>
<td>3</td>
<td>Vitamin B-12</td>
<td>Vit B-12 0.1 % WS</td>
<td>0.020</td>
<td>0.011</td>
</tr>
<tr>
<td>4</td>
<td>Vitamin B-1</td>
<td>Thiamine mononitrate</td>
<td>9.0</td>
<td>5.4</td>
</tr>
<tr>
<td>5</td>
<td>Vitamin B-2</td>
<td>Riboflavin</td>
<td>6.0</td>
<td>3.6</td>
</tr>
<tr>
<td>6</td>
<td>Niacin</td>
<td>Niacin amide</td>
<td>50</td>
<td>33.0</td>
</tr>
<tr>
<td>7</td>
<td>Zinc</td>
<td>Zinc oxide</td>
<td>80</td>
<td>60.0</td>
</tr>
<tr>
<td>8</td>
<td>Vitamin A</td>
<td>Vitamin A Palmitate SD</td>
<td>1.0</td>
<td>0.6</td>
</tr>
</tbody>
</table>

*These levels of fortification take into consideration intrinsic content of nutrients in the unfortified wheat flour as well as process variation.

5.2 Fortification requirements during marketing

It is recognized that some losses in nutrients may occur during marketing and so the levels to be applied at retail take into account these losses. The regulatory levels at retail are provided in Table 4.

Table 4 — Fortification requirements during marketing

<table>
<thead>
<tr>
<th>S/N</th>
<th>Nutrient</th>
<th>Fortification compound</th>
<th>Amount (mg/kg)</th>
<th>Label claim (mg per 100 g)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Minimum</td>
<td>Maximum</td>
</tr>
<tr>
<td>1</td>
<td>Folate</td>
<td>Folic acid</td>
<td>1.1</td>
<td>3.3</td>
</tr>
<tr>
<td>2</td>
<td>Iron</td>
<td>Sodium iron EDTA</td>
<td>27</td>
<td>51</td>
</tr>
<tr>
<td>3</td>
<td>Vitamin B-12</td>
<td>Vit B-12 0.1 % WS</td>
<td>0.01</td>
<td>0.029</td>
</tr>
<tr>
<td>4</td>
<td>Vitamin B-1</td>
<td>Thiamine mononitrate</td>
<td>4.6</td>
<td>14.2</td>
</tr>
<tr>
<td>5</td>
<td>Vitamin B-2</td>
<td>Riboflavin</td>
<td>3.3</td>
<td>9.6</td>
</tr>
<tr>
<td>6</td>
<td>Niacin</td>
<td>Niacin amide</td>
<td>30</td>
<td>87</td>
</tr>
<tr>
<td>7</td>
<td>Zinc</td>
<td>Zinc oxide</td>
<td>60</td>
<td>116</td>
</tr>
<tr>
<td>8</td>
<td>Vitamin A</td>
<td>Vitamin A Palmitate SD</td>
<td>0.5</td>
<td>1.4</td>
</tr>
</tbody>
</table>

5.3 Formulation of fortification premix for addition of vitamins and minerals to wheat flour

5.3.1 The fortification premix shall be formulated so that when 550 g of fortification premix is added to 1 metric ton of wheat flour, the levels described as factory addition level in Table 2 are achieved during production.

5.3.2 All fortificants, including diluents, shall be of acceptable standard and conform to the following: United States Pharmacopoeia (USP), British Pharmacopoeia (BP), Pharmacopoeia Europa (PE), National Formulary (NF), Food Chemical Codex (FCC) and FAO/WHO.

5.3.3 The fortification premix shall be labelled according to labelling recommendations in MS 19 and MS 1632.

5.3.4 Large factories with good mixing facilities can add the fortification premix directly while small fortification plants may have to dilute the premix with flour before adding to ensure consistent mixing. Regardless of the mixing facilities, fortification premix should be added at the rate of 550 g to 1 metric ton flour. Specifications for the fortification premix are provided in Table 5.
Table 5 — Specification of fortification premix formulation

<table>
<thead>
<tr>
<th>S/N</th>
<th>Nutrient</th>
<th>Fortification compound</th>
<th>Concentration of nutrient (g/kg)</th>
<th>Concentration of fortificant (g/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Folate</td>
<td>Folic acid (Activity 90 % min)</td>
<td>4</td>
<td>4.0</td>
</tr>
<tr>
<td>2</td>
<td>Iron</td>
<td>Sodium iron EDTA</td>
<td>55</td>
<td>419.6</td>
</tr>
<tr>
<td>3</td>
<td>Vitamin B-12</td>
<td>Vit B-12 0.1 % WS</td>
<td>0.04</td>
<td>36.4</td>
</tr>
<tr>
<td>4</td>
<td>Vitamin B-1</td>
<td>Thiamine mononitrate (Activity 81 % min)</td>
<td>16</td>
<td>20.2</td>
</tr>
<tr>
<td>5</td>
<td>Vitamin B-2</td>
<td>Riboflavin</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>6</td>
<td>Niacin</td>
<td>Niacin amide (Activity 99 % min)</td>
<td>91</td>
<td>91.8</td>
</tr>
<tr>
<td>7</td>
<td>Zinc</td>
<td>Zinc oxide (Activity 80 % min)</td>
<td>145</td>
<td>181.8</td>
</tr>
<tr>
<td>8</td>
<td>Vitamin A</td>
<td>Vitamin A Palmitate spray dried or equivalent</td>
<td>2</td>
<td>24.2</td>
</tr>
<tr>
<td>9</td>
<td>Diluent</td>
<td>To make up 1kg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note 1:** Vitamin A shall be added in the form of stabilized Vitamin A palmitate that has been spray dried or any equivalent form, containing 75,000 micrograms RE activity per gram (0.075 % min). The vitamin A palmitate shall have storage stability such that no more than 20 % of its original activity will be lost when stored for 21 days at 45 ºC in a well closed container at a level 2.5kg in wheat flour having moisture content in the range of 13.5 % to 14.5 %.

**Note 2:** 1 Retinol Equivalent RE = 1 microgram retinol = 3.33 IU

### 6 FOOD ADDITIVES

Only those food additives listed under this product in MS 237, may be used and only within the limits specified.

### 7 CONTAMINANTS

#### 7.1 Heavy metals

Fortified wheat flour shall comply with the maximum levels for contaminants that are specified for the product in MS 302.

#### 7.2 Pesticide residues

Fortified wheat flour shall comply with those maximum residue limits in the latest database established by the Codex Alimentarius Commission.

#### 7.3 Mycotoxins

Fortified wheat flour shall comply with those maximum mycotoxin limits in the latest database established by the Codex Alimentarius Commission.

### 8 HYGIENE

Fortified wheat flour shall be manufactured in premises complying with the hygienic practices stipulated in MS 21.

### 9 PACKAGING AND LABELLING

#### 9.1 Packaging

9.1.1 Fortified wheat flour shall be packaged in containers, which will safeguard the hygienic, nutritional, technological, and organoleptic qualities of the product.
9.1.2 The containers, including packaging material, shall be made of substances that are safe and suitable for their intended use. They shall not impart any toxic substance or undesirable odour or flavour to the product.

9.1.3 When the product is packaged in sacks, these must be clean, sturdy and strongly sewn or sealed.

9.2 Labelling

In addition to the requirements of MS 19, MS 624 and MS 625, the following specific labelling requirements shall apply and shall be legibly and indelibly marked:

9.2.1 Name of the product. The name of the product to be shown on the label shall be “Fortified wheat flour.”

9.2.2 Labelling of non-retail containers

Information for non-retail containers shall either be given on the container or in accompanying documents, except that the name of the product, lot identification and the name and address of the manufacturer or packer shall appear on the container. However, lot identification and the name and address of the manufacturer or packer may be replaced by an identification mark, provided that such a mark is clearly identifiable with the accompanying documents.

9.2.3 Fortification. The label shall include the minimum level of fortification made, as per Table 4.

10 METHODS OF SAMPLING AND ANALYSIS

10.1 Sampling

10.1.1 Sampling for food fortification. Sampling shall be in accordance with international provision of AOAC and the ECSA manual for monitoring of wheat flour fortified with vitamins and minerals.

10.1.2 Sampling for physical and chemical requirements and microbiological limits. Sampling shall be in accordance with MS 145.

10.2 Methods of analysis

10.2.1 Methods of analysis for vitamins and minerals. Determination of the quantity of vitamins and minerals in fortified wheat flour shall be undertaken in accordance with the ECSA manual of laboratory methods for fortified foods.

10.2.3 Methods of analysis for physical and chemical requirements. The methods of test shall be in accordance with the methods outlined in Table 1 and any other methods established by the Codex Alimentarius Commission.
THE MALAWI BUREAU OF STANDARDS
The Malawi Bureau of Standards is the standardizing body in Malawi under the aegis of the Ministry of Industry. Set up in 1972 by the Malawi Bureau of Standards Act (Cap: 51:02), the Bureau is a parastatal body whose activities aim at formulating and promoting the general adoption of standards relating to structures, commodities, materials, practices, operations and from time to time revise, alter and amend the same to incorporate advanced technology.

CERTIFICATION MARK SCHEME
To bring the advantages of standardization within the reach of the common consumer, the Bureau operates a Certification Mark Scheme. Under this scheme, manufacturers who produce goods that conform to national standards are granted permits to use the Bureau’s “Mark of Quality” depicted below on their products. This Mark gives confidence to the consumer of the commodity’s reliability.