



DRAFT EAST AFRICAN STANDARD

Food fortification premix and fortificants — Specification

EAST AFRICAN COMMUNITY

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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.

The committee responsible for this document is 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.

In elaborating this standard, inputs received from manufacturers, suppliers, World Health Organization guidelines on flour fortification, National and International Publications and Nigerian Standard NIS 475: 2015 are hereby acknowledged.

Introduction

Micronutrient deficiencies in developing countries are widespread, particularly deficiencies of Iron, Vitamin A, Iodine, Folic acid and Zinc.

Food fortification is an excellent option for delivering specific nutrient to people where one or more centrally controlled and regulated foods are eaten on a regular basis and in sufficient amounts by a large number of people.

To be successful, however, all food fortification programmes require a system to be in place to ensure that the food being fortified contains the desired amounts of micronutrients.

Food fortification premix and fortificants — Specification

1 Scope

This Draft East African Standard specifies the requirements, sampling and test methods for food fortification premix and fortificants intended for use in wheat flour, maize flour, composite flour, blended flour, sugar, salt, fat spreads and edible fats and oils.

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.

CODEX STAN 192, *General standard for food additives*

EAS 38, *Labelling of pre-packaged foods — General requirements*

EAS 39, *Hygiene in the food and drink manufacturing industry — Code of practice*

ISO 20633, *Infant formula and adult nutritionals — Determination of vitamin E and vitamin A by normal phase high performance liquid chromatography*

AOAC 2015.002, *Standard Method Performance RequirementsSM (SMPRs) for Total Vitamin B1 (Thiamin) in Infant and Adult/ Pediatric Nutritional Formula*

AOAC 2015.003, *Standard Method Performance RequirementsSM (SMPRs) for Total Vitamin B2 (Riboflavin) in Infant and Adult/ Pediatric Nutritional Formula*

AOAC 2015.004, *Standard Method Performance RequirementsSM (SMPRs) for Total Vitamin B3 (Niacin) in Infant and Adult/ Pediatric Nutritional Formula*

AOAC 961.15, *Method modification for liquid chromatographic determination of thiamine, riboflavin, and pyridoxine in medical foods.*

AOAC 2004.05, *AOAC Official Method 2004.05 Total Folates in Cereal*

AOAC 952.20, *Cobalamin (Vitamin B12 Activity) in vitamin preparations — Microbiological methods*

ISO 6869, *Animal feeding stuffs — Determination of the contents of calcium, copper, iron, magnesium, manganese, potassium, sodium and zinc — Method using atomic absorption spectrometry*

AOAC 960.45, *Vitamin A in margarine. Spectrophotometric method*

3 Terms and definitions

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

3.1

fortification

practice of deliberately adding micronutrient(s), 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

3.2

fortification premix

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

3.3

fortificant

compound which contains essential micronutrient intended to be added to a food

3.4

food vehicle

food products to which micronutrients are added such as wheat flour, maize flour, composite flour, blended flour, sugar, salt, fat spreads and edible fats and oils

3.5

indicator

measurable value used to verify that a process is working according to specifications. For example, feed rate can be used as an indicator to verify the correct functioning of a fortification process

3.6

micronutrient

natural or synthesized vitamin, mineral or a trace element that is essential for normal growth, development and maintenance of life and of which a deficiency will be detrimental to health

3.7

diluent

suitable, inert, edible food grade carrier for micronutrients

3.8

overage

refers to the additional amount of fortificant added to the premix/ food to compensate for losses that do occur during processing, distribution and storage, which will ensure the fortified food delivers the targeted level of nutrients at the time the food is used

4. Requirements

4.1 General requirements

4.1.1 The addition rate for the premix or the fortificants to the final products shall be declared on the package.

4.1.2 The Minimum nutrient level in the premix or fortificant shall be the active form of the nutrient added as declared in the specification Tables 1, 2, 3 and 4 of this standard.

4.2 Specific requirements

4.2.1 The food fortification premix and food fortificants is formulated at an addition rate of 500 g/MT so to comply with Table 1, 2, 3 and 4 for the respective food vehicle.

NOTE Where a premix is presented at declared addition rate other than 500 g/MT, the minimum limits on nutrients in the premix shall be calculated as shown in each of the table.

4.2.2 The results of analysis shall be the nutrient content of the premix or fortificant as specified in the micronutrient column of each table.

Table 1 — Premix for milled maize products, blended flours and composite flour

Micronutrient	Fortificant compound	g/Kg of premix ^{1,2}	Test method
Vitamin A as Retinol	Vitamin A (Retinyl) palmitate, spray-dried or equivalent, 7.5 % retinol, min	1	ISO 20633
Vitamin B ₁	Thiamin Mononitrate, activity level, 81 %, min	7	AOAC 2015.002
Vitamin B ₂	Riboflavin, activity level, 90.5 %, min.	5	AOAC 2015.003
Vitamin B ₃	Niacinamide, activity level, 99 %, min	36	AOAC 2015.004
Vitamin B ₆	Pyridoxine, activity level, 82 %, min.	5	AOAC 961.15
Folates	Folic acid, activity level, 100 %, min.	1	AOAC 2004.05
Vitamin B12	Vitamin B12 (Water soluble), activity level, 0.1 %, min.	0.02	AOAC 952.20
Iron	NaFeEDTA, activity level, 12.5 % Fe, min.	45	ISO 6869
	Ferrous fumarate activity level, 32 %, min		
Zinc	Zinc oxide, activity level, 80 %, min.	76	ISO 6869
<p>1 Refer to clause 4.2.2</p> <p>2 in premix of different declared addition rate as per clause 4.1.1, Nutrient content in g/kg of premix shall be calculated as shown below for each of the micronutrient:</p> $\text{Nutrient in g/Kg} = \left(\frac{a}{b}\right) \times c$ <p>where</p> <p>a is 500g/MT,</p> <p>b is the declared addition rate in g/MT of premix,</p> <p>c is g/kg of nutrient of premix specified in this table (column 3).</p>			

Table 2 — Premix for wheat flour

Micronutrient	Fortificant compound	g/Kg of premix ¹	Test Method
Vitamin A as Retinol	Vitamin A (Retinyl) palmitate, spray-dried or equivalent, 7.5 % retinol, min	1	ISO 20633
Vitamin B1	Thiamin Mononitrate, activity level, 81 %, min.	11	AOAC 2015.002
Vitamin B2	Riboflavin, activity level, 90.5 %, min.	8	AOAC 2015.003
Vitamin B3	Niacinamide, activity level, 99 %, min	60	AOAC 2015.004
Vitamin B6	Pyridoxine, activity level, 82 %, min.	7	AOAC 961.15
Folates	Folic acid, activity level, 100 %, min.	3	AOAC 2004.05
Vitamin B12	Vitamin B12 (Water soluble), activity level, 0.1 %, min.	0.02	AOAC 952.20
Iron	NaFeEDTA, activity level, 12.5 % Fe, min.	45	ISO 6869
	Ferrous fumarate activity level, 32 %, min		
Zinc	Zinc oxide, activity level, 80 %, min.	92	ISO 6869
¹ Refer to clause 4.2.2 ² in premix of different declared addition rate as per clause 4.1.1, Nutrient content in g/kg of premix shall be calculated as shown below for each of the micronutrient: $\text{Nutrient in g/Kg} = \left(\frac{a}{b}\right) \times c$ <p>where</p> <p>a is 500g/MT,</p> <p>b is the declared addition rate in g/MT of premix, and</p> <p>c is g/kg of nutrient of premix specified in this table (column 3).</p>			

Table 3 — Vitamin A fortificant for sugar

Micronutrient	Fortificant Compound	g/kg of premix ^{1,2}	Method of test
Vitamin A as Retinol	Retinyl Palmitate (1.7 M IU/g oil or 1 M IU/g)	12	AOAC 960.45
<p>1Refer to clause 4.2.2</p> <p>2 in fortificant of different declared addition rate as per clause 4.1.1, Nutrient content in g/kg of premix shall be calculated as shown below for each of the micronutrient:</p> $\text{Nutrient in g/Kg} = \left(\frac{a}{b}\right) \times c$ <p>where</p> <p>a is 500g/MT</p> <p>b is the declared addition rate in g/MT of premix</p> <p>c is g/kg of nutrient of premix specified in this table (column 3)</p>			

Table 4 — Vitamin A fortificant for edible oils, fats and fat spreads

Micronutrient	Fortificant Compound	g/kg of premix ^{1,2}	Method of test
Vitamin A as Retinol	Retinyl Palmitate (1.7 M IU/g oil or 1 M IU/g)	48	AOAC 960.45
<p>1Refer to clause 4.2.2</p> <p>2 in fortificant of different declared addition rate as per clause 4.1.1, Nutrient content in g/kg of premix shall be calculated as shown below for each of the micronutrient:</p> $\text{Nutrient in g/Kg} = \left(\frac{a}{b}\right) \times c$ <p>where,</p> <p>a is 500g/MT,</p> <p>b is the declared addition rate in g/MT of premix, and</p> <p>c is g/kg of nutrient of premix specified in this table (column 3).</p>			

Table 5 — Potassium iodate fortificant for salt

Micronutrient	Fortificant Compound	g/kg of premix ^{1,2}	Method of test
Iodine	Potassium iodate	69	AOAC 960.45

<p>1 Refer to clause 4.2.2</p> <p>2 in fortificant of different declared addition rate as per clause 4.1.1, Nutrient content in g/kg of premix shall be calculated as shown below for each of the micronutrient:</p> $\text{Nutrient in g/Kg} = \left(\frac{a}{b}\right) \times c$ <p>where</p> <p>a is 500g/MT,</p> <p>b is the declared addition rate in g/MT of premix, and</p> <p>c is g/kg of nutrient of premix specified in this table (column 3).</p>			

5 Contaminants

5.1 Heavy metals

The premix shall be free from heavy metals in amounts, which may represent a hazard to human health.

6 Food additives

When used, food additives shall be in accordance with CODEX STAN 192.

7 Hygiene

Food fortification premix and fortificants shall be manufactured, prepared and handled in accordance with EAS 39.

8 Weights and measures

Food fortification premix and fortificants shall comply with the Weights and Measures Regulations of the respective Partner States.

9 Packaging

9.1 Food fortification premix and fortificants shall be packaged in containers, which will safeguard the hygienic, nutritional, technological, and organoleptic qualities of the product.

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

9.3 The product package must be clean, sturdy and strongly sewn or sealed.

10 Labelling

In addition to the provisions of EAS 38, the following information shall be legibly and indelibly included on the label of the container or package:

- a) name of the product: for flour premixes, it shall be “wheat flour premix” or “maize/composite flour premix”. For sugar and fats/oils it shall be labelled as “Vitamin A fortificant for xx”, where xx may either be sugar or oils, for salt it shall be as potassium iodate fortificant;
- b) nutrient compound used;
- c) addition rate shall be declared;
- d) Instructions/direction for use;
- e) name and location address of the manufacturer;
- f) batch/lot number and identification code;
- g) net weight (in metric system);
- h) date of manufacture and Best before date;
- i) premix Composition; and
- j) storage condition.

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